IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated, *Plaintiff*, *vs.* MEDICIS PHARMACEUTICAL CORP., IMPAX LABORATORIES, INC., LUPIN LIMITED, LUPIN PHARMACEUTICALS INC., RANBAXY PHARMACEUTICALS, INC., RANBAXY INC., RANBAXY LABORATORIES, LTD. ("RANBAXY"), SANDOZ INC., MYLAN INC., MATRIX LABORATORIES LTD., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., BARR LABORATORIES, INC., AND VALEANT PHARMACEUTICALS INTERNATIONAL, INC. *Defendants.*	Civil Action No. CLASS ACTION JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC" or "Plaintiff"), on behalf of itself and all others similarly situated, files this Class Action Complaint ("Complaint") against Defendants Medicis Pharmaceutical Corp. ("Medicis"), Valeant Pharmaceuticals International, Inc. ("Valeant") (Medicis and Valeant together are "Medicis"), Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (a wholly owned subsidiary of Teva Phar-

maceuticals USA, Inc.) ("Teva"), Impax Laboratories, Inc. ("Impax"), Mylan Laboratories, Inc. and Mylan's majority owned subsidiary Matrix Laboratories Ltd. ("Mylan"), Lupin Limited and Lupin Pharmaceuticals Inc. ("Lupin"), Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., Ranbaxy Laboratories, Ltd. ("Ranbaxy"), Sandoz Inc. ("Sandoz") (Teva, Impax, Mylan, Lupin, Ranbaxy, and Sandoz, collectively, are the "Generic Defendants," and together with Medicis, the "Defendants"). Plaintiff alleges as follows based on: (a) personal knowledge; (b) the investigation of Plaintiff's counsel; and (c) information and belief:

NATURE OF ACTION

1. This is a civil antitrust action under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, seeking treble damages and other relief arising out of Defendants' overarching anticompetitive scheme to exclude competition from the market for minocycline hydrochloride extended release tablets, a prescription drug for the treatment of acne marketed by Medicis under the brand name Solodyn. As alleged below, Medicis orchestrated a multi-faceted scheme, undertaken alone and with, between, and among the Generic Defendants, to improperly restrain trade, and maintain, extend, and abuse Medicis's monopoly power in the market for minocycline hydrochloride extended release tablets to the detriment of Plaintiff and the Class of direct purchasers it seeks to represent (as defined below), causing them to pay overcharges.

2. Solodyn was approved by the Federal Food and Drug Administration ("FDA") in 2006 and quickly became Medicis's largest selling, "flagship" product. Medicis knew, however, that Solodyn—which generated approximately half of Medicis's sales by 2007—was especially vulnerable to a rapid, near-complete loss of sales upon the entry into the market of less expensive, generic versions of Solodyn. First, because Solodyn contains the old antibiotic ingredient minocycline, Solodyn did not qualify for a period of regulatory exclusivity that would have

prevented the FDA from approving a generic Solodyn product. For example, Solodyn was not eligible for the 5-year marketing exclusivity granted to new chemical entities, nor was it eligible for the 3-year marketing exclusivity granted to brand name drugs approved pursuant to new clinical studies. And, critically, Medicis was not able to obtain the Hatch-Waxman Act's automatic 30-month stay of FDA approval of generic Solodyn products merely by listing a patent in the FDA "Orange Book" and suing any generic manufacturer that filed a Paragraph IV certification asserting that Medicis's patents were invalid and/or not infringed. Second, the only patent that purportedly covered Solodyn for at least the first three years it was marketed, U.S. Patent No. 5,908,838 ("'838 Patent"), was invalid and/or unenforceable and thus unlikely to prevent a generic Solodyn product from coming to market in advance of patent expiry.

3. Recognizing the dire threat that generic competition posed to its Solodyn sales in the near-term, Medicis formulated a multi-step plan, described in detail below, to protect Solodyn from generic competition using any means necessary, whether lawful or unlawful. Medicis's Chief Executive Officer, Jonah Shacknai, even boasted in calls with investors about Medicis's multi-part strategy to prevent generic competition through every and any conceivable means—a plan that Medicis in fact successfully implemented to impede and delay generic competition to Solodyn.

4. In December 2007, Impax notified Medicis that Impax had filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Solodyn. Impax further told Medicis that: (a) the '838 Patent is invalid because Medicis withheld from the patent examiner highly relevant prior art; and (b) if Medicis attempted to enforce the invalid '838 Patent against Impax, such a suit would be an objectively and subjectively baseless sham in violation of the antitrust laws. Impax then filed a lawsuit seeking a declaratory judgment that the

'838 Patent is invalid and not infringed by Impax. Medicis, however, had its strategy to thwart generics at the ready, which it proceeded to unveil.

5. First, while Impax's declaratory judgment action was pending, Medicis filed an objectively and subjectively baseless sham petition to the FDA solely to delay FDA approval of Impax's generic Solodyn ANDA. In its petition, Medicis asked the FDA not to approve any generic version of Solodyn without requiring in vivo bioequivalence testing for each of the 45mg, 90mg, and 135mg Solodyn strengths. Medicis had no objectively reasonable basis for this request, and no reasonable petitioner could have expected to succeed on the merits of this request because, *inter alia*, Medicis's argument as to why its potential competitors needed to conduct certain bioequivalence tests in order to receive FDA approval was the exact *opposite* of the position Medicis had taken when it successfully convinced FDA not to require Medicis itself to conduct such bioequivalence tests to gain approval of its own Solodyn products. Medicis filed the petition, despite its lacking any merit whatsoever, because Medicis knew that the mere filing of the petition would delay FDA approval of Impax's ANDA. Medicis's petition did, in fact, delay FDA approval of Impax's ANDA – FDA approved Impax's ANDA on the same day, February 3, 2009, that FDA denied Medicis's petition.

6. Second, on November 28, 2008—before the FDA ruled on Medicis's baseless petition and approved Impax's generic Solodyn for marketing, and before the court could rule on Impax's legal challenge to the validity of the '838 Patent—Medicis and Impax entered into an unlawful Exclusion Payment Agreement. Under this unlawful Agreement, Medicis paid Impax at least $55 million to drop the patent challenge and stay out of the market for three years, until November 2011 ("Medicis/Impax Exclusion Payment Agreement"). Impax did, in fact, delay marketing its generic 45mg, 90mg and 135mg Solodyn products until November 26, 2011.

Moreover, Impax's entry at that late date was practically worthless to purchasers because, as discussed below, by that time Medicis had destroyed demand for Solodyn in 45mg, 90mg, and 135mg strengths as part of its anti-generic strategy.

7. Third, after Congress amended the Food Drug and Cosmetic Act to apply certain Hatch-Waxman Act provisions, like the 30-month stay of FDA approval of ANDAs containing Paragraph IV certifications to Orange Book-listed drugs, to drugs containing old antibiotics like Solodyn, Medicis improperly submitted the '838 Patent to the FDA for listing in the Orange Book, and then initiated and maintained sham patent suits against multiple potential generic competitors solely in an attempt to automatically stay FDA approval of those generic manufacturers' ANDAs for up to 30 months. Medicis knew that its listing of the '838 Patent was improper because, *inter alia*: (a) the '838 Patent was eligible for Orange Book listing only if Medicis could reasonably assert a claim of patent infringement if a person not licensed by Medicis engaged in the manufacture, use, or sale of Solodyn; and (b) Medicis could not reasonably assert such a claim against potential generic competitors because the '838 Patent was invalid and/or unenforceable in light of Medicis's deceptive misrepresentations and omissions to the patent examiner regarding Medicis's first slow release minocycline product, Dynacin. No reasonable litigant could have realistically expected Medicis's patent infringement suits on the invalid and/or unenforceable '838 Patent to succeed.

8. Fourth, as part and parcel of Medicis's improper Orange Book listing and the sham patent suits, Medicis filed yet another objectively and subjectively baseless sham petition to delay FDA approval of any additional generic Solodyn ANDAs. This time, Medicis argued that it was entitled to a 30-month stay of FDA approval of any ANDA seeking approval to market a generic version of Solodyn after it sued any such generic applicants for patent infringement following

notification of their Paragraph IV certifications—even for ANDAs that had been filed before Medicis listed the '838 Patent in the Orange Book. Medicis had no objectively reasonable basis for this request, and no reasonable petitioner could have expected to succeed on the merits of this request because, *inter alia*, Medicis's argument was premised on the Hatch-Waxman Act as it existed in 1984, not in 2009. Since 2003, 30-month stays do not apply to an ANDA certifying to a patent that was listed *after* the ANDA was filed. Medicis filed the petition, despite its lacking any merit whatsoever, because Medicis knew that the mere filing of the petition would delay FDA approval of any ANDA that is the subject of the petition. Medicis's petition did, in fact, delay FDA approval of at least Teva's generic Solodyn ANDA—the FDA approved Teva's ANDA on the same day, March 17, 2009, that FDA denied Medicis's second baseless petition.

9. Fifth, to prevent any generic version of 45mg, 90mg or 135mg strength Solodyn from coming to the market before Impax entered in November 2011 (and to give Medicis time to switch the market, as discussed below), Medicis orchestrated additional Exclusion Payment Agreements with, between, and among potential competitors Teva, Sandoz, and Mylan. Medicis paid Teva, Sandoz, and Mylan substantial sums as the quid pro quo for their agreement to drop their challenges to the '838 Patent and delay market entry of their generic versions of 45mg, 90mg or 135mg strength Solodyn until November 2011. The payments came in the form of: (a) substantial profits from authorized limited sales, during which Medicis guaranteed to each of Teva, Sandoz, and Mylan that, seriatim, each of them would have the only generic version of Solodyn on the market at any given time; and (b) Medicis's agreement not to distribute an "authorized generic" version of Solodyn to compete against Teva, Sandoz, or Mylan during these serial periods of exclusivity.

10. Sixth, having literally bought itself more time without generic competition, Medicis used that time to delay generic competition beyond November 2011. Medicis implemented an anticompetitive switch strategy, known in the industry as "product hopping," pursuant to which Medicis introduced versions of Solodyn in 55mg, 65mg, 80mg, 105mg, and 115mg strengths—which did not face imminent generic competition. The new dose strengths of Solodyn offered no benefits to consumers over the 45mg, 90mg or 135mg (*i.e.*, "legacy") strengths. The only "benefit" of the new dose strengths was to Medicis; because the expected generic Solodyn products in legacy strengths would not be "AB-rated" to branded Solodyn in the new strengths, pharmacists could not legally substitute less-expensive generic Solodyn in one of the legacy strengths when presented with a prescription for Solodyn in one of the new strengths.

11. Merely introducing the new dose strengths was not enough, however, to ensure Medicis's stranglehold on the market for minocycline hydrochloride extended release tablets. Rather, Medicis aggressively destroyed demand for Solodyn legacy strengths and then converted that demand to the new Solodyn strengths using its army of sales force detailers. And then, in July 2011, shortly before legacy generics were scheduled to enter the market, Medicis stopped shipping branded Solodyn in legacy strengths altogether. As a result, by the time generic Solodyn products entered the market in November 2011, the prescription base for Solodyn in legacy strengths was virtually nonexistent. Branded Solodyn—now available in only the new strengths—had successfully thwarted generic competition yet again.

12. Medicis was still not done. When potential generic competitors finally neared FDA approval for generics in the new Solodyn strengths, Medicis paid off those competitors too. It was particularly crucial for Medicis to insulate 65mg and 115mg Solodyn from generic competition because, after the predatory product-switch strategy, those strengths comprised approximately

three-quarters of Solodyn sales. Medicis accomplished this through a two-part strategy: (a) Medicis paid Teva, the first-filer with respect to the 65mg and 115mg strengths, to drop its challenge to the patents, delay entry, and "park" its 180-day exclusivity; and (b) Medicis paid the later-filing generic manufacturers, Ranbaxy, Mylan, and Lupin, not to unplug the bottleneck that Medicis and Teva created on the 65mg and 115mg strengths. Medicis's agreement with Lupin, pursuant to which Medicis paid Lupin at least $20 million, with the potential for $38 million in additional payments, also "parked" Lupin's 180-day exclusivity with respect to 55mg Solodyn, for which Lupin was the first ANDA-filer.

13. But for Defendants' anticompetitive scheme (including the agreements), generic Solodyn in legacy strengths would have entered the market far earlier than they did. Other generic versions of Solodyn, including an authorized version marketed directly or indirectly by Medicis, would have also entered the market, driving down generic prices even further. Moreover, but for the anticompetitive scheme (including the agreements), Medicis would never have begun selling Solodyn in 55mg, 65mg, 80mg, 105mg, and 115mg strengths, or if it had, it would have made far fewer sales. Had generic entry already occurred, purchasers would have already switched to the lower-priced generics, and Medicis would not have been able to substantially reduce the number of prescriptions for Solodyn in legacy strengths available for generic substitution.

14. Plaintiff brings this action as a class action on behalf of all those who purchased Solodyn directly from Medicis in the United States, including Puerto Rico (collectively the "Direct Purchaser Class") (see Class Definition below). Plaintiff seeks a judgment declaring Medicis's and the Generic Defendants' conduct to be unlawful under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

PARTIES

A. Plaintiff

15. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a wholesale drug cooperative located at 50 Jet View Drive, Rochester, New York 14624. RDC purchased Solodyn directly from Medicis during the Class Period as defined below, and was injured by the illegal conduct described herein.

B. Defendants

16. Defendant Medicis Pharmaceutical Corp. ("Medicis") is a brand drug manufacturer incorporated under the laws of the State of Delaware, with its principal place of business at 7720 N. Dobson Road, Scottsdale, Arizona. Medicis develops, manufactures, and markets pharmaceuticals and related products in the United States. Medicis's common stock is traded on the New York Stock Exchange under the symbol MRX.

17. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

18. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva USA is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States. Teva Pharmaceuticals USA is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

19. Defendant Teva Pharmaceutical Industries Ltd. is a corporation, headquartered and having a place of business at 5 Basel St., Petach Tikva 49131, Israel, engaged in the development,

manufacturing, marketing, and distribution of pharmaceuticals. Through its subsidiaries, a large portion of Teva Pharmaceutical Industries Ltd.'s sales are in the United States, and Teva Pharmaceutical Industries Ltd. has major manufacturing operations in the United States. Teva Pharmaceutical Industries Ltd. is the parent company of Teva Pharmaceuticals USA.

20. Defendant Barr Laboratories, Inc. ("Barr") is a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., and is a Delaware corporation with offices located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Barr is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

21. Defendants Teva USA, Teva Pharmaceutical Industries Ltd., and Barr are referred to collectively as "Teva."

22. Defendant Mylan Inc. is a generic drug manufacturer incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

23. Defendant Matrix Laboratories Ltd. is a majority owned subsidiary of Mylan Inc. with its principal place of business at 1-1-15/1, Alexander Road, Secunderabad 500-003, India.

24. Defendants Mylan Inc. and Matrix Laboratories Ltd. are referred to collectively as "Mylan."

25. Defendant Lupin Limited, is a business entity organized under the laws of India with its principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

26. Defendant Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals, Inc. is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

27. Defendants Lupin Limited and Lupin Pharmaceuticals Inc. are referred to collectively as "Lupin."

28. Defendant Ranbaxy Pharmaceuticals, Inc. is a company organized and existing under the laws of Florida, with its principal place of business at 9431 Florida Mining Blvd. East, Jacksonville, Florida. Ranbaxy Pharmaceuticals, Inc. is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

29. Defendant Ranbaxy Laboratories Limited is a public limited liability company organized and existing under the laws of India, with its principal place of business located at Plot 90, Sector 32, Gurgaon-122001 (Haryana), India.

30. Defendant Ranbaxy, Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

31. Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, and Ranbaxy, Inc. are referred to collectively as "Ranbaxy." Ranbaxy is engaged in the worldwide production and distribution of pharmaceuticals, primarily generic products, including in the United States.

32. Defendant Sandoz Inc. ("Sandoz") is a Colorado corporation with its principal place of business at address at 506 Carnegie Center, Princeton, NJ 08540. Sandoz is in the business of developing, manufacturing, and marketing pharmaceutical products, primarily generic products, in the United States.

33. Defendant Valeant Pharmaceuticals International, Inc. ("Valeant") is a Canadian corporation with its principal place of business at 2150 St. Elzéar Blvd. West, Laval, Quebec Canada H7L 4A8. Valeant's United States headquarters are located at 700 Route 202/206 Bridgewater, New Jersey 08807. Valeant acquired Medicis in an all-cash transaction in December 2012. The combined company's commercial dermatology operations are located in Scottsdale, Arizona and operate under the name Medicis, a division of Valeant, with its dermatology research and development operations in Laval, QC, Scottsdale, AZ and Petaluma, CA, and corporate support functions primarily based in New Jersey. Valeant directly and independently participated in the conduct alleged herein.

34. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful anticompetitive scheme and illegal restraints of trade alleged herein, and were authorized, ordered, and/or performed by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs, within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

JURISDICTION AND VENUE

35. This action is filed, and these proceedings are instituted, under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries (in the form of overcharges) sustained by Plaintiff and members of the Class of direct purchasers of Solodyn from Medicis resulting from the violation by the Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

36. Venue is proper in this Court under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391, because Defendants transact business in this District. A substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

REGULATORY BACKGROUND

C. Characteristics of the Prescription Pharmaceutical Marketplace

37. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's product choice and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

38. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Solodyn, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

39. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

40. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The market imperfections and marketing practices described above allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

D. Generic Versions of Brand Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand Versions

41. Manufacturers of generic drugs typically price their versions of brand drugs significantly below the brand price. These price differentials prompt pharmacists to liberally and substantially substitute generic versions for the brand counterparts whenever generics are available and substitution is legally permissible. In particular, generic drugs that are pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to their brand name counterparts are given an "AB" rating by the FDA. Pharmacists substitute a less-expensive AB-rated generic product for the corresponding brand product unless the doctor has indicated that the

prescription for the brand product must be "dispensed as written" or the patient objects. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generics accelerates.

42. All states permit (and some states require) pharmacists to automatically substitute an AB-rated generic drug for the corresponding brand name drug unless the doctor has stated that the prescription for the brand name product must be dispensed as written.

43. Many third party payors (such as health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. In addition, many consumers routinely switch from a branded drug to an AB-rated generic drug once the generic becomes available. Consequently, AB-rated generic drugs typically capture a significant share of their branded counterparts' sales, causing a rapid and significant reduction of the branded drug's unit and dollar sales.

44. Once a generic equivalent enters the market, the generic quickly captures sales of the brand drug, often capturing 80% or more of unit sales within the first six months. About one year after market entry, the generic version often takes more than 90% of the brand's unit sales and sells for approximately 15% of the brand price.

45. Generic competition enables purchasers at all levels of the pharmaceutical supply chain, including all members of the proposed Class, to: (a) purchase generic versions of a drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price. Until a generic manufacturer enters the market, however, there is no bioequivalent generic drug to compete with the brand drug, and therefore the brand manufacturer can continue to profit from supracompetitive pricing, without losing its brand sales. Consequently, brand drug manufacturers have a strong

incentive to use various tactics, including those alleged above, to delay the introduction of generic competition into the market.

46. Brand manufacturers are well aware of generics' rapid erosion of their previously monopolized market. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means.

E. The Regulatory Structure for FDA Approval of Generics

47. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-392) ("FDCA"), manufacturers that create a new, pioneer drug must obtain the FDA's approval to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information regarding applicable patents.

48. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

49. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

50. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent and pharmaceutically equivalent to the brand-name drug.

51. As a counter-balance to this abbreviated process for bioequivalent generic drugs, Hatch-Waxman provided a number of benefits to brand-drug manufacturers. For example, Hatch-Waxman grants a 5-year period of exclusivity (regardless of any patent protection) to NDAs for products containing chemical entities never previously approved by FDA either alone or in combination. Hatch-Waxman also grants a 3-year period of exclusivity (regardless of any patent protection) for a drug product that contains an active ingredient that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application.

52. Hatch-Waxman also streamlined the process for a brand manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions, the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand drug for up to 30 months.

53. When the FDA approves a brand manufacturer's NDA, the FDA lists any compound patents which (according to the brand manufacturer) claim the approved drug, in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." 21 U.S.C. §355(j)(7)(A)(iii). In the case of method-of-use patents, the FDA lists in the Orange Book any patents that (according to the brand manufacturer) claim the drug for its approved method of use. Method-of-use patents are properly submitted to FDA for Orange Book listing only if the manufacturer could reasonably assert a claim of patent infringement against a person who was not licensed by the owner to manufacture, use, or sale the drug. 21 U.S.C.A. § 355 (b)(1). In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand manufacturer

may list other new patents in the Orange Book as related to the NDA, if the brand manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the drug for approved methods of use (for method-of-use patents).

54. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand drug), a generic manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

> a. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
>
> b. that the patent for the brand drug has expired (a "Paragraph II certification");
>
> c. that the patent for the brand drug will expire on a particular date and the generic manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
>
> d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

55. If a generic manufacturer files only paragraph I, II, or III certifications, then it can take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

56. If a generic manufacturer files a Paragraph IV certification asserting that a patent listed in the Orange Book is invalid or will not be infringed, a brand manufacturer often has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic

drug. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then in certain circumstances the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification, a brand manufacturer often may delay the FDA's approval of the generic drug and its entry into the market. During the pendency of an applicable 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay. FDA does not grant tentative approvals when 30-month stays are inapplicable, however.

57. Congress also created incentives for generic manufacturers to seek approval of generic alternatives to branded drugs and challenge weak patents. Hatch-Waxman grants to the first generic manufacturer to file a substantially complete ANDA containing a Paragraph IV certification to at least one Orange Book-listed patent (a "first filer") a 180-day period of market exclusivity ("180-day exclusivity"), during which the first filer enjoys temporary freedom from competition from other generic versions of the drug approved via ANDA. This 180-day exclusivity period (or any period during which there is only one generic version of a brand name drug on the market) is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. The entry of a second generic (or additional generics) can

cut the original generic price by half or more. Selling six months' worth of a generic drug for a product such as Solodyn, as the only generic on the market, can be worth hundreds of millions of dollars in profit.

58. Several provisions of Hatch-Waxman did not apply to Solodyn until October 8, 2008, after the effective date of the so-called "QI Act." Pub. L. No. 110-379, 122 Stat. 4075 (2008) (codified in relevant part at 21 U.S.C. § 355(v)). Before that date, drugs like Solodyn that contained an active moiety like minocycline hydrochloride that had been the subject of a marketing application received by FDA before November 21, 1997 (and thus known as an "old antibiotic") were exempted from the market exclusivity, patent listing, patent certification, and 30-month stay provisions of Hatch-Waxman. The QI Act brought such old antibiotics within those provisions of Hatch-Waxman.

59. The QI Act included three transitional provisions. Those provisions: (1) require antibiotic drug NDA sponsors to submit to FDA for Orange Book listing information on applicable patents within 60 days of enactment of the QI Act; (2) require FDA to list those patents in the Orange Book not later than 90 days after the enactment of the QI Act; and (3) create "first applicant" status (for 180-day exclusivity purposes) for each ANDA applicant that not later than 120 days after enactment of the QI Act amends a pending application to contain a Paragraph IV certification to a newly listed antibiotic drug patent. Thus, if multiple ANDA applicants each submitted a Paragraph IV certification to a newly listed antibiotic drug patent within the requisite time period, they would each be "first applicants" within the meaning of Hatch-Waxman and share 180-day exclusivity. If any one of the first applicants launched its generic product, the start of 180-day exclusivity would be triggered for all of the first applicants.

F. Manufacturers' "Gaming" of the Regulatory Structure

1. Abuse of the 30-month stay provision

60. Brand manufacturers can "game the system" by listing patents in the Orange Book (even patents that are not eligible for listing) and then suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the patent is clearly invalid, or the generic's product non-infringing) in order to obtain the automatic 30-month stay and delay final FDA approval of the ANDA for up to two and a half years. Brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition, rather than to enforce valid patents against infringing products. Generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in 73% of the cases studied.

2. Abuse of FDA's Citizen Petition Process

61. Persons can submit a citizen petition to the FDA at any time in order to express genuine concerns about safety, scientific, or legal issues regarding a product. Under these regulations, any person or entity, including a pharmaceutical manufacturer, may file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. The person or entity submitting such a citizen petition is required, under FDA regulations, to include all information and views on which the petitioner relies, as well as all information and data known to the petitioner which is unfavorable to the petition.

62. Federal regulations provide a 180-day period for the FDA to respond to each citizen petition. 21 C.F.R. § 10.30. The FDA usually takes much more than 180 days, however, because reviewing and responding to these petitions is often a resource-intensive and time-consuming task requiring the FDA, in addition to its already-existing workload, to (a) research the

citizen petition's subject matter, (b) examine scientific, medical, legal, public health, and safety concerns, and occasionally economic issues, (c) consider public responses, and (d) coordinate internal agency review and clearance of the petition response.

63. These activities can and do strain the FDA's limited resources. It was the well-known practice of the FDA during the Class Period to consider and respond to a citizen petition before approving an ANDA product that was the subject of the citizen petition and to delay approval of the ANDA pending response to a citizen petition, particularly when the petition had been filed by a brand manufacturer asserting (whether correctly or not) a public health or safety concern.

64. Brand manufacturers have commonly used the filing of citizen petitions as a tactic to extend their monopolies. Taking advantage of FDA's practice of delaying ANDA approvals while it evaluates petitions, brand manufacturers have routinely submitted petitions to the FDA that do not raise legitimate concerns about the safety or effectiveness of generic products. This tactic delays final ANDA approval, sometimes for substantial periods, while the FDA evaluates the petition.

65. The brand manufacturer's cost of filing sham citizen petitions is trivial compared to the value to the manufacturer of securing an additional period of monopoly profits.

66. All of this is common knowledge in the pharmaceutical industry.

67. FDA officials have acknowledged ongoing abuses of the petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency, he had "seen several examples of Citizen Petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the

petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

68. In July 2006, Gary Buehler, Director of the FDA's Office of Generic Drugs, Center for Drug Evaluation and Research ("CDER"), testifying before Congress on abuses of the citizen petition process by brand manufacturers, stated that of forty-two citizen petitions raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered FDA's policies." Of these forty-two petitions, only three led to a change in the FDA's policy on the basis of data or information submitted in the citizen petition.

69. Other federal agencies have also recognized the ongoing abuse of the petition process by brand manufacturers. The Federal Trade Commission's ("FTC") then-Chairman Jon Leibowitz lamented that the petition process is "susceptible to systematic abuse," and that "[i]t is no coincidence that brand companies often file these petitions at the eleventh hour before generic entry and that the vast majority of citizen petitions are denied."

70. In fact, this tactic became such a problem that in 2007 Congress was forced to step in and revise the FDCA to provide that the FDA could not delay approval of a pending ANDA because of a petition, and that the FDA was require to take final action on such a petition not later than 180 days after it is submitted. However, the FDA can postpone action if it determines that "a delay is necessary to protect the public health." 21 U.S.C. § 355(q)(1). The FDA frequently invokes this provision, as even baseless petitions require time and resources to evaluate.

3. Product Hopping

71. As discussed above, in order to be substitutable for a branded product at the pharmacy counter, and approvable by FDA as AB-rated to a particular branded product, a generic product must be, among other things, "pharmaceutically equivalent" (same dosage form and

strength) and "bioequivalent" (exhibiting the same drug absorption characteristics) as the branded product.

72. FDA regulations, which are concerned only with safety and effectiveness and not with effects on competition, permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to A_1, for no reason other than to prevent generic competition to A. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer might get approval for A_1 and use various tactics to cause physicians to write prescriptions only for A_1 instead of A. The brand manufacturer's modification of A to A_1 may thereafter cause the manufacturer of the generic version of A to garner few or no sales, because its product is not substitutable for A_1.

4. Exclusion Payments and Bottlenecks

73. In order to delay the drastic loss of monopoly profits from their branded drugs, some unscrupulous brand manufacturers design schemes whereby they buy their way out of competition from generics and the chance that the brand patents might be invalidated or found not to be infringed. Brand manufacturers sometimes compensate the generic manufacturers to defer entering the market and to drop their challenges to the patents. Brand and generic manufacturers often try to disguise these payments, using various subterfuges as a way to try to escape liability under the antitrust laws.

74. Although these Exclusion Payment Agreements purport to settle patent infringement suits, in making a payment to the accused infringer, the patentee is using the strength of its wallet, as opposed to the strength of its patents, to obtain the agreement of the generic

manufacturers to delay entry into the market and to avoid a court decision as to whether the patent is invalid or not infringed. The brand manufacturer effectively shares some of its monopoly profits with the generic manufacturers as the quid pro quo for their agreement to delay competition. The brand and generic manufacturers split between themselves the savings that earlier generic entry would have brought to consumers.

75. Moreover, the first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch their generic versions of the product until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

76. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity, at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment

that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

77. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic manufacturer filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in Paragraph IV litigation.

78. The brand manufacturer and first filer frequently take various steps to fortify the bottleneck by making it less economically viable for subsequent filers to trigger the first filer's exclusivity. For instance, Exclusion Payment Agreements often include "poison pill" provisions, which allow the first filer to enter the market before the later date otherwise agreed with the brand manufacturer, if a subsequent filer succeeds in entering the market before that later date. The co-conspirators disclose these terms publicly, thus broadcasting to subsequent filers that even if they incur the substantial expense involved in dislodging the bottleneck, they will be guaranteed to face competition from at least the first filer, and likely others. By eliminating all possibility that subsequent filers will enjoy any period of de facto exclusivity, these poison pill provisions

significantly reduce the value to subsequent filers of obtaining a court decision that would break the bottleneck. Thus, where a first filer has "parked" its 180-day exclusivity and agreed to a poison pill provision, subsequent filers have comparatively less to gain by obtaining a court decision of invalidity and/or non-infringement and are therefore willing to settle for much less time on the market than they otherwise would have.

5. No-Authorized-Generic Agreements

79. No-Authorized-Generic Agreements are Exclusion Payment Agreements, exploiting the 180 days of exclusivity given to a first filing generic. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

80. In its recent study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

81. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug

purchasers such as Plaintiff and the Class benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

82. Given the significant negative effect of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers such as Plaintiff and the Class of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

83. Agreements not to compete with an authorized generic can take many forms. According to the FTC Study, one such form includes agreements whereby the brand manufacturer agrees to exclusively supply the first-filing generic with the authorized generic product. The result is no competition between an authorized generic and the first-filing generic's product for a period of time.

FACTUAL ALLEGATIONS

84. Solodyn accounted for about half of Medicis's entire annual revenue. Medicis unlawfully protected those revenues by executing an anticompetitive scheme that used every one of the monopolistic tools discussed above. The anticompetitive scheme and its elements are described in more detail below.

G. Solodyn

1. Product Description

85. Solodyn is the brand name, prescription acne drug manufactured and sold by Medicis for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris

in patients age 12 and older. Non-nodular acne is the bright red pimples on the surface layer of the skin. Solodyn uses a once daily, minocycline hydrochloride extended release tablet with a unique dissolution rate to treat this form of acne.

86. Minocycline is an industry mainstay antibiotic ingredient that is approved to treat acne. Minocycline is a broad-spectrum tetracycline antibiotic and is the most lipid-soluble of the tetracycline-class antibiotics, giving it the greatest penetration into the prostate and brain, but also the greatest amount of central nervous system-related side effects, such as vertigo. Other side effects include diarrhea, skin discoloration, and autoimmune disorders that are not seen with other drugs in the class. Minocycline is not a naturally-occurring antibiotic, but was synthesized semi-synthetically from natural tetracycline antibiotics by Lederle Laboratories in 1972, which subsequently marketed it under the brand name Minocin.

87. Antibiotics like minocycline go after the particular bacterial culprits responsible for non-nodular acne. P.acnes is the anaerobic bacterium species that is widely thought to cause this particular form of acne inflammation. The strain has the ability to change, perpetuate, or adapt to the abnormal cycle of inflammation, oil production, and inadequate sloughing activities of acne pores. In contrast to antibiotic acne medications, isotretinoin medications such as Roaccutane, Accutane, and Claravis treat acne primarily by reducing the secretion of oils from the glands.

88. Solodyn's active ingredient is minocycline hydrochloride, which is a semi-synthetic derivative of tetracycline. Solodyn's once daily, extended release tablet regimen purports to be more convenient (and potentially more effective) for patients than other tetracycline drugs or isotretinioins, which require multiple doses per day. Extended-release medications like Solodyn have special coatings or ingredients that control how fast the drugs are released from the pill into the patient's body, allowing the patient to take these medications only once or twice a

day. Medicis touts Solodyn's once daily, extended release feature to differentiate it from other acne treatments, emphasizing that Solodyn is "the only branded oral minocycline approved for once daily dosage in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older" and "the first and only extended release minocycline with eight FDA-approved dosing strengths."

89. Solodyn's pharmacological profile, and thus its side effect and efficacy profile, is different than other tetracycline and/or antibiotic products that doctors prescribe to treat the same or similar conditions. Those other drugs are not AB-rated to Solodyn, cannot be automatically substituted for Solodyn by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Solodyn at competitive prices, and thus are not economic substitutes for, nor reasonably interchangeable with, Solodyn. Medicis's 2008 10-K confirms: "SOLODYN® is not bioequivalent to any other minocycline products, and is in no way interchangeable with other forms of minocycline."

2. Solodyn's FDA Approval and Patent Background

90. On June 30, 2005, Medicis submitted NDA No. 50-808 seeking FDA approval to market Solodyn extended release tablets in 45mg, 90mg, and 135mg ("legacy") strengths for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older. The FDA approved Medicis's Solodyn NDA on May 8, 2006.

91. As discussed below, FDA also subsequently granted approval to Medicis to market Solodyn in five additional strengths: 55mg, 65mg, 80mg, 105mg, and 115mg. FDA approved the 65mg and 115mg strengths on July 23, 2009, and approved the 55mg, 80mg, and 105mg strengths on August 7, 2010.

92. Medicis currently has six patents relating to Solodyn.

93. U.S. Patent No. 5,908,838 (the "'838 Patent") was issued by the United States Patent and Trademark Office on June 1, 1999 to Eugene H. Gans and assigned to Medicis. Medicis asserts that the '838 Patent covers "methods for the treatment of acne" through the "use of oral tetracycline antibiotics." The '838 Patent expires on February 19, 2018.

94. At the time Medicis submitted and FDA approved its NDA for Solodyn in the legacy strengths, Congress had not yet enacted the QI Act and, thus, the '838 Patent was not and could not have been listed in the Orange Book. After the QI Act became effective on October 8, 2008, Medicis submitted, on December 3, 2008, the '838 Patent for listing in the Orange Book in connection with its Solodyn NDA. Under clear and unambiguous law, Medicis was not entitled to any 30-month stay under the Hatch-Waxman Act for any ANDAs submitted by generic manufacturers for the Solodyn legacy strengths before Medicis listed the '838 Patent on December 3, 2008.

95. U.S. Patent No. 7,541,347 (the "'347 Patent") was issued to Medicis on June 2, 2009. Medicis then submitted the '347 Patent for listing in the Orange Book in connection with its Solodyn NDA. Medicis asserts that the '347 Patent relates to the use of the 90mg controlled-release oral dosage form of minocycline to treat acne. The '347 Patent expires in 2027.

96. U.S. Patent No. 7,544,373 (the "'373 Patent") was issued on June 9, 2009. Medicis then submitted the '373 Patent for listing in the Orange Book in connection with its Solodyn NDA. Medicis asserts that the '373 Patent relates to the composition of the 90mg dosage form. The '373 Patent expires in 2027.

97. U.S. Patent No. 7,790,705 (the "'705 Patent") was issued on September 7, 2010. Medicis subsequently submitted the '705 Patent for listing in the Orange Book. Medicis asserts that the '705 patent relates to all strengths of Solodyn and expires in 2025.

98. U.S. Patent No. 7,919,483 (the "'483 Patent") was issued on April 5, 2011 and was listed in the Orange Book thereafter. Medicis asserts that the '483 Patent "covers methods of using a controlled-release oral dosage form of minocycline to treat acne, including the use of our product SOLODYN in all eight currently available dosage forms." The '483 Patent expires in 2027.

99. U.S. Patent No. 8,268,804 (the "'804 Patent") was issued on September 8, 2012 and was listed in the Orange Book thereafter. Medicis asserts that the '804 Patent covers a method for the treatment of acne and relates to all strengths of Solodyn. The '804 Patent expires in 2025. The '804 Patent had not yet issued at the time of any of the unlawful conduct alleged herein.

100. The '838, '347, '373, '705, '483, and '804 patents are referred to collectively herein as the "Solodyn Patents." The '347, '373, '705, '483, and '804 patents are referred to collectively herein as the "Later Issued Patents."

101. As discussed more fully below, none of the Solodyn Patents would have prevented generic Solodyn products from entering the market before those patents expired. At the time Medicis filed its first sham citizen petition, filed sham lawsuits with respect to the '838 Patent, and entered the Exclusion Payment Agreements with Impax and Teva, none of the Later Issued Patents had issued. And the invalid and/or unenforceable '838 Patent alone would not have kept generics from entering the market before its expiration in 2018 for all the reasons discussed below. Moreover, although the '347 and '373 patents had issued by the time of Medicis's Exclusion Payment Agreements with Sandoz and Mylan, and the '705 and '483 patents had also issued by the time of Medicis's Exclusion Payment Agreement with Lupin, none of those patents would have prevented earlier generic entry. But for Medicis's anticompetitive conduct, Medicis would not have prosecuted any of the Later Issued Patents to issuance, because Medicis would have lost

its profit motive to do so once generics entered and purchasers switched to the less expensive generics.

102. But even if the Later Issued Patents actually issued, they would not have prevented generics from entering the market earlier absent Medicis's unlawful conduct. No automatic 30-month stay of FDA approval applied to any of the Generic Defendants' ANDAs that were submitted before the Orange Book listing of any of the Later Issued Patents. Moreover, each of the Later Issued Patents is weak, and was likely to have been adjudicated invalid, unenforceable, or not infringed.

3. Solodyn Sales

103. Since obtaining FDA approval in 2006, Solodyn has proven to be very lucrative to Medicis. The annual U.S. sales for Solodyn between 2007 and 2011 are as follows:

YEAR	SALES
2007	$247M
2008	$316M
2009	$479M
2010	$673M
2011	$761M

104. As of 2011, Medicis announced that Solodyn was "[t]he #1 dermatology medication by dollars in the world and the #1 most prescribed branded dermatology product in the U.S. by prescriptions and dollars."

105. Solodyn was Medicis's "flagship" product, representing approximately half of Medicis's sales.

H. Solodyn's Particular Vulnerability to Generics

106. Despite Solodyn's success, Medicis recognized that Solodyn was particularly vulnerable to the drastic loss of sales that would accompany the advent of AB-rated generic

competition to Solodyn because: (1) no regulatory exclusivity applied that would have prevented FDA from approving AB-rated generic Solodyn products; and (2) the '838 patent— for may years, the only patent shielding Solodyn from competition—was invalid and/or unenforceable.

1. Absence of Any Regulatory Exclusivity

107. Solodyn contains as its active ingredient the "old antibiotic" minocycline, which has been marketed since at least the early 1970's. As a result, the various periods of marketing exclusivity granted to certain brand manufacturers with approved NDAs, such as new chemical entity exclusivity or new clinical trial exclusivity, did not apply to Solodyn.

108. Moreover, from the time Medicis obtained FDA approval for Solodyn in 2006 until the passage of the QI Act in 2008, the Paragraph IV and 30-month stay provisions of Hatch Waxman did not apply to Solodyn. Because those provisions did not apply, Medicis could not obtain a 30-month stay of FDA regulatory approval of AB-rated generic versions of Solodyn simply by filing a patent infringement suit within 45 days of receiving notice of an ANDA containing a Paragraph IV certification to an Orange Book-listed patent for Solodyn.

2. Solodyn's "On-Sale Bar" Problem

109. Medicis had a problem because it could not patent the chemical compound for Solodyn; in fact, the claimed invention had been "on sale" prior to Medicis's attempt to patent it and therefore could not be patented. While Medicis's minocycline drug product branded as Solodyn was itself an "old antibiotic" it was not Medicis's first slow release minocycline product. That was a product called Dynacin, which Medicis sold as early as 1992.

110. Further, as will be explained more fully below, Medicis used research on its 1992 Dynacin product to generate data for the patent application that eventually issued as the '838

Patent. This is the same patent that Medicis would later claim covered Solodyn and protected it from generic competition.

111. Beginning in November 1992 and significantly more than one year before filing the '838 Patent application, Medicis sold minocycline hydrochloride capsules for the treatment of acne in the United States. These capsules were sold under the trade name Dynacin. Dynacin was sold by Medicis and was prescribed and used by patients in the United States before February 18, 1997 for the purpose of treating acne.

112. Sometime before October 1997, the named inventor of the '838 Patent, Eugene H. Gans, performed a study comparing the side effects, including vestibular side effects, of Dynacin capsules with another commercially available minocycline hydrochloride product, Vectrin. The study compared these two minocycline hydrochloride products in order to study the effect of the in vitro dissolution rates on the occurrence and magnitude of vestibular side effects in vivo. Vectrin released its minocycline almost immediately in vitro, and anecdotal reports from dermatologists indicated that Vectrin produced significant vestibular side effects in some patients. Dynacin, on the other hand, had a slow in-vitro dissolution and was not known to cause similar vestibular side effects.

113. The results of that study were published in a 1997 article entitled, "A Comparison of the Side Effects Produced by Vectrin and Dynacin After Normal Dosing" in Clinical Acne Reviews (the "Dynacin Study"). Individuals at Medicis knew about the Dynacin Study because the Dynacin Study was described in Clinical Acne Reviews as a Medicis publication. In addition, Dr. Gans, who worked as a Medicis consultant at the time, was listed as an author of the Dynacin Study.

114. The results of the Dynacin Study demonstrated, *inter alia*, that patients taking Dynacin had a reduced incidence of vestibular side effects over those taking Vectrin; the study reported a total of 27 incidences of vestibular symptoms in the Vectrin treatment group compared to 5 incidences in the Dynacin treatment group. The Dynacin Study authors, including the only named inventor on the '838 patent—Dr. Gans—hypothesized that the difference in vestibular side effects was due to the difference in dissolution rates between the fast dissolving dosage form (Vectrin) and the slower dissolving dosage form (Dynacin).

3. The '838 Patent's Unenforceability and Invalidity

115. Using the data from the Dynacin Study, Medicis filed the application that eventually issued as the '838 Patent but in doing so did not tell the U.S. Patent and Trade Office ("USPTO") that public use of Dynacin occurred before February 18, 1997, that Dynacin had been sold before February 18, 1997, or that the data that formed the basis for the '838 Patent was entirely based on Dynacin and the prior Dynacin Study.

116. Medicis's filing of the patent application that led to the '838 Patent triggered the legal duty of candor to the USPTO, including the duty to disclose information material to patentability. "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned." 37 C.F.R. § 1.56(a) (July 1, 1999); Manual of Patent Examining Procedure § 2001 (7th ed. July 1998). Applicants before the USPTO have a duty to disclose "all information known to that individual to

be material to patentability" promptly, generally before the first office action by the USPTO. 37 C.F.R. § 1.59 (July 1, 1999).

117. The '838 Patent claims a method for the treatment of acne that results in the reduction of vestibular side effects, *e.g.*, vertigo, dizziness or blurred vision, following administration of oral tetracycline antibiotics in a slowly dissolving dosage form. Until June 2009, the '838 Patent was the only patent that purportedly covered Solodyn.

118. Claim 1 of the '838 Patent as it originally issued describes Dr. Gans' alleged invention:

> 1. A method of reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotics, comprising administering the oral tetracycline antibiotic in a slowly dissolving dosage form.

Not surprisingly, the Dynacin product that Medicis had sold since at least February 18, 1997 was encompassed by this claim, because it was based on research on the very same Dynacin product. Given the breadth of this and other similar claims in the '838 Patent, Medicis, Dr. Gans, and/or the prosecuting attorneys knew this to be the case but misrepresented and/or withheld this information from the USPTO with deceptive intent.

119. Some of the data in the Dynacin Study and the '838 Patent are identical. For example, table 2 of the '838 Patent describes the exact same results that were reported in the Dynacin Study. Despite the data being identical between Table 2 of the '838 Patent and the Dynacin Study, all reference to the prior art Dynacin was removed when the data was presented in the application for the '838 Patent. In fact, the only data included within the specification of the '838 Patent was data that came from the Dynacin Study but without any attribution or explanation that the 1992 Dynacin product was available and on sale before February 18, 1997. In essence, the

'838 Patent and the Dynacin Study both report a study conducted with the identical methodology, results, and data for the symptoms, severity, number of time intervals, and severity category for each of the identified instances of vestibular side effects. The slower dissolving dosage form used in the study of vestibular effects reported in the '838 Patent was Medicis's Dynacin capsules. Yet Dr. Gans, Medicis, and/or the prosecuting attorneys intentionally and deceptively omitted from the '838 Patent application and supporting materials any and all references to Dynacin. Medicis, Dr. Gans, and/or the prosecuting attorneys intentionally omitted this critical information because they knew that the prior public use and sale of Dynacin since at least 1992 would have been a bar to patentability.

120. Dr. Gans, Medicis, and/or the prosecuting attorneys chose to deliberately misrepresent or omit this potential on sale bar to the USPTO during prosecution of the '838 Patent. Specifically, the facts that Dynacin was publicly used, sold, and/or offered for sale in the United States prior to one year before the filing of the '838 Patent application were misrepresented or improperly withheld with deceptive intent. In addition, the only data submitted with the '838 Patent was data derived from experiments conducted using Dynacin, but the specification of the '838 Patent had all reference to the 1992 Dynacin product carefully extricated from the data submitted to the USPTO and no one associated with Medicis took any steps to make the examiner aware of these and other material facts.

121. In addition, the Dynacin Study itself was never disclosed to the USPTO. The fact that Medicis and Dr. Gans knew in 1997 that a controlled extended release composition of minocycline hydrochloride (such as Dynacin) was on sale and would reduce vestibular side effects as later claimed in the '838 Patent would have been relevant to a reasonable examiner under 37

C.F.R. §1.56, but Medicis, Dr. Gans, and/or the prosecuting attorneys deliberately withheld this information from the USPTO during the prosecution of the ’838 Patent.

122. Dr. Gans, Medicis, and/or the prosecuting attorneys chose to deliberately misrepresent or omit with deceptive intent that Dynacin capsules were a controlled and extended release form of minocycline hydrochloride that was available prior to February 18, 1997 and that Dynacin itself was actually used in the study of vestibular side effects reported in the ’838 Patent.

123. Further, Dr. Gans, Medicis, and/or the prosecuting attorneys made the decision to misrepresent or deliberately omit with deceptive intent the Dynacin Study during prosecution of the ’838 Patent. The portion of the Dyancin Study that was included in the specification of the ’838 Patent had all reference to the prior art Dynacin and the Dyancin Study carefully extricated. As a result, the ’838 Patent was obtained by knowingly and willfully misrepresenting facts to the USPTO.

124. A reasonably examiner would have considered each of these misrepresentations and deliberate omissions material to the patentability of one or more of the claims of the ’838 Patent.

125. Moreover, Medicis, Dr. Gans, and/or the prosecuting attorneys—all of whom had a duty to disclose under 37 C.F.R. §1.56—deliberately omitted certain material information contained in the Dynacin Study from the ’838 Patent. A reasonable examiner would have considered the study data omitted from the ’838 Patent material to the patentability of one or more claims of the ’838 Patent because, *inter alia*, the omitted data cast doubt on the utility of the claims of the invention. The materiality of the information omitted from the ’838 Patent suggests that data was cherry-picked from the Dynacin Study as published and that certain unhelpful data was intentionally and fraudulently withheld from the USPTO.

126. In addition to being unenforceable due to inequitable conduct, the specter of invalidity hung over the '838 Patent after it was issued on June 1, 1999. In June 2008, an undisclosed party submitted to the USPTO a Request for Reexamination of the '838 Patent. Patent reexamination is the procedure by which a granted patent is reexamined by a primary examiner in the USPTO to determine whether the prior art raises a substantial question of patentability. During the August 2008 Reexamination Proceedings before USPTO, Medicis canceled claims 1-2, 5-11, and 15-18; amended claims 3, 4, 12, and 13 to be independent; and provided new claims 19-34. Although the USPTO ultimately reissued the '838 Patent on June 1, 2010—after Medicis entered its Exclusion Payment Agreements with Impax, Teva and Sandoz—none of the original '838 Patent claims survived without amendment, demonstrating that Medicis recognized that the '838 Patent was likely invalid as originally issued. Moreover, as discussed above, the '838 Patent (both as originally issued and reissued) was likely invalid due to the public use and sale of Dynacin prior to February 18, 1997.

127. Accordingly, the '838 Patent was invalid and/or unenforceable and thus unlikely to prevent a generic Solodyn product from coming to market in advance of patent expiration. This fact was not lost on Medicis, which cautioned investors in 2007 that its "failure to obtain additional patent protection could adversely affect our ability to deter generic competition, which would adversely affect Solodyn revenue."

128. With respect to the '838 Patent, Dr. Gans, Medicis, and/or the prosecuting attorney made false representations or deliberate omissions of highly material information to the USPTO examiner with the intent to deceive the USPTO. The examiner was justified in relying on the statements made by Dr. Gans, Medicis, and/or the prosecuting attorney and was justified in believing that if there were material information known to those involved in the prosecution this

information would have been brought to the attention of the examiner under the applicant's duty to disclose information material to the patentability of the '838 Patent. Had the examiner known of the misrepresented and omitted information the examiner would not have issued the '838 Patent because such information was material to whether the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States," and therefore could be anticipatory prior art to the application that led to the '838 Patent. 35 U.S.C. § 102(b).

129. To make matters worse, with full knowledge of the infirmity of the '838 Patent, as more fully described below, Medicis continued in litigation with Impax from January to November of 2008 until Medicis ultimately negotiated an Exclusion Payment Agreement, and then later engaged in additional litigation that involved the '838 Patent with several other generic drug manufacturers. Medicis continued to assert the patent against generic competitors despite knowledge that the '838 Patent was procured by fraud and was invalid and/or unenforceable.

I. Medicis's Multi-Part Strategy to Thwart Generics

130. Because Solodyn was critical to Medicis's overall financial performance and was particularly susceptible to the threat of competition from generics, Medicis developed multiple unlawful tactics to prevent, delay, or impair competition from generic Solodyn products. As Medicis explained to its investors: "you can be sure that in every conceivable respect, we are attempting to protect Solodyn," Medicis at Credit Suisse Healthcare Conference (Nov. 14, 2007), "keeping it alive as long as we can," Medicis at Merrill Lynch 19th Global Pharmaceutical, Biotechnology & Medical Device Conference (Feb. 7, 2008). Medicis's Chief Executive Officer, Jonah Shacknai, even boasted that it had "hired a couple of [law] firms that I think are vicious" to

go after generics and prop up the Solodyn brand. Medicis Earnings Conference Call (Feb. 28, 2007).

131. Then, during an earnings call on February 27, 2008, Medicis CEO Shacknai specifically identified some of the steps Medicis planned to take in order to impair generic competition. Shacknai outlined Medicis's "three-part strategy," to protect Solodyn from generic competition, which included "intellectual property," "regulatory" and "commercial" components. First, Medicis would seek to enforce the '838 Patent, and any other patents it could convince the USPTO to grant, against any potential generic competitors. Second, Medicis would file citizen petitions with the FDA with respect to the bioequivalence requirements for generic versions of Solodyn, as well as other potential regulatory matters, which would delay FDA approval of generic Solodyn products. Third, Medicis would develop "other generations of Solodyn" in order to prevent the automatic substitution of AB-rated generics for Solodyn in the event that its other tactics failed to prevent FDA approval of generic Solodyn products. Mr. Shacknai characterized each of the "three elements . . . as part of an interrelated and fairly complex strategy to defend the brand to the utmost of our ability."

132. Once potential generic competitors to Solodyn became a real and imminent threat, Medicis systematically employed each of these strategies—as well as the unlawful Exclusion Payment Agreements discussed herein—to delay and impair competition from generic versions of Solodyn.

J. Impax's Attempt to Enter the Market

133. On or about October 5, 2007, Impax submitted to the FDA its ANDA 90-024 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths. Because there were no Orange Book-listed patents for Solodyn at the time Impax submitted its ANDA,

Impax was not required by Hatch Waxman to notify Medicis of its application to market generic Solodyn.

134. On December 20, 2007, however, Impax notified Medicis of the generic Solodyn ANDA filing and requested that Medicis provide Impax with a covenant not to sue under the '838 Patent in connection with Impax's ANDA 90-024. Impax informed Medicis that any attempt by Medicis to enforce the '838 Patent against generic versions of Solodyn would be "clearly improper, since the claims of the '838 patent issued only because the patent examiner was not aware of highly relevant prior art during prosecution of the '838 patent." Impax further notified Medicis that "[i]f Medicis were to attempt to enforce the '838 patent against IMPAX. . . such an effort would be objectively and subjectively baseless, and would give rise to potential antitrust liability." In order to assist Medicis's consideration of a covenant not to sue, and to support Impax's position that its generic Solodyn products were not covered by any valid claim of the '838 Patent, Impax offered to give Medicis access to the relevant portions of ANDA 90-024.

135. Medicis failed to grant Impax's requested covenant not to sue or to respond to Impax's offer of confidential access. Consequently, on January 15, 2008, Impax filed a complaint for declaratory judgment in the United States District Court for the Northern District of California seeking a declaration that the claims of the '838 Patent are invalid and not infringed by Impax.

136. The price of Medicis's shares on the New York Stock Exchange plunged dramatically—a 12% percent drop, its biggest decline in seven years of U.S. trading—after Medicis disclosed the Impax ANDA filing in an 8-K filed January 15, 2008, the same day that Impax brought suit.

137. On March 5, 2008, Medicis moved to dismiss Impax's declaratory judgment complaint, arguing that no justiciable Article III controversy existed because (a) Impax had not

begun the commercial marketing of its generic Solodyn products and was thus not at risk of incurring patent infringement damages; (b) there could be no automatic 30-month stay of FDA approval of Impax's generic Solodyn products and thus Impax could not suffer any injury that might arise from such a stay; and (c) no conduct of Medicis was preventing Impax from marketing its generic Solodyn products.

138. Opposing Medicis's motion to dismiss, Impax emphasized, *inter alia*: (a) Medicis's repeated threats to preserve its monopoly position with respect to Solodyn by aggressively enforcing the '838 Patent against potential generic competitors through the use of "vicious" patent litigation; and (b) the public's interest in increasing competition in the drug industry and obtaining generic drugs at lower prices.

139. Before the court could decide whether Impax had standing to challenge the '838 Patent, however, Medicis implemented the next in a series of unlawful tactics which were designed to, and did, delay and impair the entry and uptake of less expensive generics.

K. Medicis's Implementation of Its Multi-Part Anticompetitive Scheme

1. Medicis's First Sham Citizen Petition

140. On March 18, 2008, while Medicis's motion to dismiss Impax's declaratory judgment complaint was still pending, Medicis filed a sham citizen petition with the FDA solely to delay approval of Impax's ANDA. The Medicis citizen petition, Number FDA-2008-P-0185, asked FDA not to approve any generic versions of Solodyn without requiring in vivo bioequivalence testing for each strength of Solodyn ("Medicis's Proportionality Petition"). Under FDA's draft bioequivalence guidelines for Solodyn (minocycline hydrochloride) extended-release tablets, posted on FDA's website in December 2007, in vivo bioequivalence testing was required

for the 135mg tablets of Solodyn, but not for 45mg and 90mg tablets as long as those strengths were "proportionally similar" to the 135mg tablets.

141. In its petition, Medicis asked that FDA not approve 45mg and 90mg strengths of any generic Solodyn products on the basis of bioequivalence testing on the 135mg strength. In support, Medicis argued that the 45mg and 90mg strengths of Solodyn *are not dose-proportional* to the 135mg strength and therefore requested that FDA designate 90mg Solodyn as a separate reference-listed drug from the 135mg strength, and that the 90mg be the focus of bioequivalence testing for all strengths other than the 135mg.

142. Medicis's argument was directly contrary to the argument it had successfully made to the FDA in order to get approval of its own Solodyn products. Medicis convinced the FDA to approve Medicis's own 45mg and 90mg products on the ground that they *are dose-proportional* to the 135mg strength. Medicis's in vivo pharmacokinetic studies demonstrated that the different strengths of Solodyn result in dose-proportional exposure. FDA therefore approved Solodyn's label, which states: "A single-dose, four-way crossover study demonstrated that all strengths of Solodyn tablets (45 mg, 90 mg, 135 mg) exhibited dose-proportional pharmacokinetics." Also based on this finding of dose-proportional exposure, FDA designated the highest approved strength of Solodyn tablets, 135 mg, as the reference standard against which generic versions of Solodyn must establish in vivo bioequivalence.

143. On February 3, 2009, FDA denied Medicis's Proportionality Petition. The FDA refused to require ANDA applicants for minocycline hydrochloride extended-release tablets to conduct in vivo bioequivalence testing on 45mg or 90mg strengths if bioequivalence is demonstrated in vivo for the 135mg strength and the generic product demonstrates appropriate grounds for testing the lower strengths using in vitro methods.

144. In denying Medicis's Proportionality Petition, FDA found that "none of the[] facts" Medicis asserted were "directly relevant to whether ANDA applicants must separately demonstrate in vivo bioequivalence to Solodyn for multiple strengths." Indeed, the FDA noted that Medicis itself had submitted data to the FDA showing that the drug's pharmokinetics were proportional to the amount of the active ingredient, the proportions of inactive ingredients notwithstanding. FDA also noted that Solodyn's own labeling states that "[a] single-dose, four-way crossover study demonstrated that all strengths of Solodyn tablets (45 mg, 90 mg, 135 mg) exhibited dose-proportional pharmacokinetics." As a result of Medicis's own studies and labeling, the FDA concluded there was in fact "dose proportional exposure in vivo," and reaffirmed its prior finding that "135 mg [Solodyn is] the reference standard against which generic versions of Solodyn must establish in vivo bioequivalence."

145. Medicis's petition was objectively baseless and a sham, made and timed as an improper attempt to slow down the FDA approval process for Impax's ANDA. As noted above, Medicis's CEO had stated publicly that Medicis would file citizen petitions as part of a campaign to delay entry by generic rivals. Merely filing a citizen petition, regardless of its merits, delays the FDA's approval process for an ANDA. As a matter of pattern and practice, the FDA does not approve an ANDA if a pertinent petition—even a baseless one—is pending. Adjudicating even a meritless citizen petition requires FDA to expend its time and resources, and the FDA will frequently cite public health concerns to take more time to evaluate such petitions, even ones which are ultimately meritless. Absent Medicis's petition, FDA would have processed Impax's ANDA more rapidly and approved it earlier.

146. On February 3, 2009, the same day that FDA denied Medicis's Proportionality Petition, FDA gave final approval to Impax's ANDA Number 90-024 for generic 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

147. But for Medicis's conduct, including the Proportionality Petition, FDA would have given final approval to Impax's ANDA before February 3, 2009.

148. Impax, however, did not launch its generic Solodyn products on February 3, 2009 despite receiving FDA approval to do so. Rather than launch its products—which Impax had represented would be in the public's interest in increasing competition in the drug industry and obtaining generic drugs at lower prices—Impax reached an anticompetitive agreement with Medicis to delay Impax's entry into the market for three years.

2. The Medicis/Impax Exclusion Payment Agreement

149. On April 16, 2008, the district court granted Medicis's motion to dismiss Impax's declaratory judgment complaint for lack of jurisdiction. The court did not address Impax's contentions concerning the validity or infringement of the '838 Patent. Impax filed its notice of appeal of the motion to dismiss decision with the United States Court of Appeals for the Federal Circuit on May 12, 2008.

150. In November 2008, while Impax's appeal and Medicis's baseless Proportionality Petition were still pending, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement. Pursuant to that Agreement, on or about November 26, 2008, Impax agreed to: (a) drop the appeal of its declaratory judgment action against Medicis; (b) admit that the '838 Patent, plus 297 unissued claims from twelve pending patent applications are valid and enforceable; and (c) admit that its activities in connection with its ANDA 90-024 infringed the '838 Patent. At the

time of the unlawful Agreement, neither the parties nor the court had addressed any of the substantive merits of the patent dispute.

151. Under the Medicis/Impax Exclusion Payment Agreement, Impax agreed to delay launching its generic Solodyn products in 45mg, 90mg, and 135mg strengths until the earlier of: (a) November 26, 2011; or (b) the date on which another generic version of Solodyn entered the market. In other words, Impax agreed to delay the launch of its generic Solodyn products until November 26, 2011 unless its right to launch earlier than then was triggered by the market entry of another generic Solodyn product.

152. As the quid pro quo for Impax's agreement to drop its challenge to the '838 Patent, Medicis agreed to pay Impax tens of millions of dollars or more. Medicis's payments to Impax under the Agreement took a variety of forms.

153. First, in December 2008, Medicis paid Impax an "upfront fee" of $40 million under the guise of a Joint Development Agreement providing for the collaboration and development of four generic dermatology products and an advanced form of Solodyn.

154. Second, the Agreement obligated Medicis to pay Impax up to $23 million in milestone payments, of which Medicis has already paid Impax $15 million.

155. Third, to the extent any products are commercialized under the Agreement, Medicis was to pay Impax royalties on sales of the "new" form of Solodyn, and Impax will receive 50% of all profits on the generic dermatology products.

156. Fourth, the Agreement granted to Impax the right to distribute an authorized generic version of the subsequent form of Solodyn for a split of the gross profits related to the sales of such authorized generic product.

157. Although Medicis and Impax characterize the payments under the Agreement as consideration for the collaboration and development of additional dermatology products, and/or for the distribution of an authorized generic version of a subsequent branded Solodyn product, that characterization is pretextual. In fact, the payments from Medicis to Impax were for Impax's agreement to delay generic competition to Solodyn for three years. Absent Impax's agreement to delay entry into the market with generic Solodyn, Medicis would not have entered the Joint Development Agreement with Impax and/or would not have agreed to the price and/or other terms that it did under those provisions of the Agreement. Medicis paid Impax for delayed market entry of generic Solodyn.

158. Impax did, in fact, delay continued marketing of its generic 45mg, 90mg, and 135mg Solodyn products until November 26, 2011 (though, as discussed below, entry at that late date was practically worthless to consumers because Medicis destroyed demand for Solodyn in 45mg, 90mg, and 135mg strengths as part of its multi-part, anti-generic strategy). Other generic manufacturers, however, were still threatening to enter the market with competing generic Solodyn products. So Medicis swiftly mitigated the threat from other potential generic competitors with additional tactics that were designed to, and did in fact, delay generic Solodyn products from entering the market.

3. Medicis's Improper Orange-Book Listing and Sham Patent Suits

159. On October 8, 2008, Congress enacted the QI Program Supplemental Funding Act (Pub. Law No. 110-379) ("QI Act"), which amended the FDCA to add new § 505(v) – "Antibiotic Drugs Submitted Before November 21, 1997" – to create certain Hatch-Waxman provisions for "old" antibiotics. The QI Act includes three transitional provisions, which: (1) require antibiotic drug NDA sponsors to submit to FDA for Orange Book listing information on applicable patents

within 60 days of enactment of the QI Act; (2) require FDA to list those patents in the Orange Book not later than 90 days after the enactment of the QI Act; and (3) create "first applicant" status (for 180-day exclusivity purposes) for each ANDA applicant that not later than 120 days after enactment of the QI Act amends a pending application to contain a Paragraph IV certification to a newly listed antibiotic drug patent.

160. On December 3, 2008, Medicis wrongfully submitted the '838 Patent for listing in the FDA Orange Book. Although the QI Act made the Orange Book listing provisions of Hatch-Waxman generally applicable to old antibiotics like Solodyn, any patents covering an antibiotic or method of using an antibiotic still had to meet all of the other requirements for Orange Book listing. Method-of-use patents are eligible for Orange Book listing only if a claim for patent infringement could reasonably be asserted against a generic manufacturer not licensed by Medicis. As Medicis knew, no reasonable claim for infringing the '838 Patent could have been asserted because, as discussed above, the '838 Patent is invalid and/or unenforceable. Yet Medicis submitted the '838 Patent for listing in the Orange Book anyway, solely as part of its plan to delay generic competition.

161. After improperly listing the '838 Patent in the Orange Book, Medicis received multiple Paragraph IV notifications in connection with multiple generic manufacturers' previously-filed ANDAs to market generic Solodyn products.

162. On or about December 5, 2008, Medicis received a notice letter from Mylan stating that its subsidiary Matrix had filed ANDA 09-0911 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths which contained a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Mylan's generic product. Mylan's subsidiary Matrix had filed its ANDA 09-0911 on September 30, 2008.

163. On or about December 8, 2008, Medicis received a notice letter from Sandoz stating that it had filed ANDA 09-0422 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths which contained a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Sandoz's generic product. Sandoz had filed its ANDA 09-0422 before December 5, 2008.

164. On or about December 23, 2008, Medicis received a notice letter from Barr stating that it had filed ANDA 65-485 seeking to market generic versions of Solodyn in 45mg, 90mg, and 135mg strengths which contained a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Barr's generic product. Barr had filed its ANDA 65-485 in April 2007.[1]

165. On January 13, 2009, Medicis filed suit against Mylan, Barr/Teva, and Sandoz in the United States District Court for the District of Delaware seeking an adjudication that the generic manufacturers infringed one or more claims of Medicis's '838 Patent by submitting to FDA their respective ANDAs for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets with Paragraph IV certifications. No reasonable litigant could have realistically expected Medicis to succeed on its claims that Mylan, Barr/Teva, Sandoz—or any generic manufacturer—infringed the invalid and unenforceable '838 Patent. Medicis filed and prosecuted the '838 Patent infringement suits discussed herein for the sole purpose of delaying generic competition.

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[1] On December 12, 2008, Medicis also received a notice letter from Impax stating that it had filed its ANDA with a Paragraph IV certification that the '838 Patent is invalid, unenforceable, and/or would not be infringed by Impax's generic product. Impax and Medicis, however, had already entered the Medicis/Impax Exclusion Payment Agreement. Because Impax, Teva, Sandoz, and Mylan had each submitted a Paragraph IV certification to the newly-listed '838 Patent within the requisite time under the transitional provisions of the QI Act, the four generic manufacturers were each entitled to share 180-day exclusivity regarding the 45mg, 90mg, and 135mg strengths of generic Solodyn.

4. Medicis's Second Sham Citizen Petition

166. Next, as part and parcel of its scheme to improperly list and assert the '838 Patent, on February 13, 2009, Medicis submitted a second baseless citizen petition to FDA, Number FDA-2009-P-0081-0004, requesting that FDA not approve for thirty (30) months, measured from the date Medicis received notice of the Paragraph IV Certification: (a) the ANDAs submitted by Mylan, Barr/Teva, and Sandoz; and (b) any other then-pending ANDA referencing Solodyn for which the applicant made a Paragraph IV certification, and for which Medicis sued for patent infringement within the requisite 45-day period ("Medicis's 30-Month Stay Petition").

167. On March 17, 2009, FDA denied Medicis's 30-Month Stay Petition, ruling that no 30-month stay of FDA approval applied because the '838 Patent was not Orange Book-listed until after the ANDAs were pending before FDA. According to FDA, Medicis's positions were "not supported by either the plain language of the QI Act or by the regulatory framework for innovator and generic drug products of which the QI Act is a part." Medicis had no objectively reasonable basis for its requests that a 30-month stay should apply to ANDAs submitted before the '838 Patent was listed in the Orange Book, and no reasonable petitioner could have expected to succeed on the merits of Medicis's 30-Month Stay Petition.

168. Conceding that nothing in the QI Act actually states that an ANDA applicant that amends its ANDA to include a Paragraph IV certification pursuant to the QI Act would be subject to a 30-month stay, Medicis's 30-Month Stay Petition raised three objectively baseless grounds as to why a 30-month stay should nonetheless be read into the Act (where it does not appear): (1) the QI Act requires application of the 30-month stay provisions of the original Hatch-Waxman Amendments as enacted in 1984, rather than the version of the statute amended by the MMA in 2003, which limits 30-month stays to only those ANDAs that are filed after a patent is Orange Book-listed; (2) ANDAs amended to contain a Paragraph IV certification to a patent that was

submitted for Orange Book listing pursuant to the QI Act should be deemed submitted to FDA on the date when the first possible application containing a Paragraph IV Certification could have been submitted (even though they were not); and (3) the patent at issue should be treated as having been submitted to FDA with the original NDA (even though it was not).

169. Regarding the first of Medicis's baseless grounds, its sole argument was based on a reference in the QI Act that "the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply" to old antibiotics. According to Medicis, because the QI Act referred once to the Hatch Waxman Act "of 1984," the 2003 amendments to the Hatch-Waxman Act should not apply and therefore 30-month stays based on patents filed after ANDA submission purportedly did not govern Medicis's 2008 patent listing or the generic Solodyn ANDAs submitted in 2007 and 2008.

170. FDA flatly rejected Medicis's argument, concluding that Congress "did not require FDA to turn back the clock to 1984," and that such an "outcome is inconsistent with the purpose of the QI Act." FDA further explained that the bare statutory reference to the Hatch Waxman Act "of 1984" did not permit the FDA to ignore the 2003 amendments, and nothing in the statutory text, legislative history, or regulatory considerations supported any different conclusion. The reference to the "Drug Price Competition and Patent Term Restoration Act of 1984" was simply "a more formal shorthand than the more common reference to "the Hatch-Waxman Amendments." Moreover, the text of the QI Act itself, which refers to other statutory provisions amended in 2003 by the MMA, was "fatal" to the argument that the original 1984 Act, rather than the law as it existed at the time, should have applied.

171. Regarding the second of Medicis's baseless grounds, Medicis argued that the QI Act recalculates the actual ANDA submission dates to be after the patent listing date. Medicis's

tortured argument goes like this: a transitional provision of the QI Act deems all ANDA applicants who timely file a Paragraph IV certification to a patent listed pursuant to the QI Act to be "first applicants" for the purpose of 180-day exclusivity; "first applicants" are defined as "an applicant that, on the first day on which a substantially complete application containing [a Paragraph IV Certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV Certification] for the drug"; thus, the ANDAs at issue must be treated as having been submitted on the first day on which the first possible ANDA containing a Paragraph IV Certification could have been submitted (which, by necessity, must have been after the patent was Orange Book-listed).

172. Again, FDA dismissed Medicis's argument. Under the MMA, 180-day exclusivity does not apply only when an ANDA contains a Paragraph IV certification to a listed patent on the date the ANDA is originally submitted to FDA. To the contrary, an ANDA that is originally submitted without a Paragraph IV certification to a listed patent, but is then amended to contain a Paragraph IV certification to a listed patent, is also eligible for 180-day exclusivity. Although the QI Act effectively treats the applicants' amendments containing Paragraph IV certifications as having been submitted on the first day on which any ANDA applicant submitted a substantially complete application that contains a Paragraph IV certification to a patent for the listed drug, the QI Act in no way recalculates the date on which the applicant originally submitted its ANDA.

173. For its third baseless argument, Medicis asserted that the patent at issue should be treated as having been submitted to FDA with the original NDA—*i.e.*, before the generic Solodyn ANDAs. Medicis relied on QI Act transitional provision 4(b)(1) which states that patent information "required to be filed with [FDA] under subsection (b)(1) or (c)(2)" of section 505 of the FDCA must be filed within 60 days after enactment of the QI Act. Medicis argued that

because those subsections of FDCA Section 505 require the patent information to be filed at the time of NDA filing, the date of its patent information submission must necessarily be moved back to the date of NDA filing, even though its NDA was submitted years before. FDA rejected Medicis's "tortured" and "strained" reading. The QI Act's reference to Section 505 was merely to the type of information that needed to be submitted. Medicis clearly understood the reasonable (*i.e.*, the FDA's, not Medicis's) interpretation of this language since Medicis submitted the type of patent information specified within the time frame specified by this section of the QI Act.

174. Medicis's 30-Month Stay Petition was baseless and a sham, made and timed solely as an improper attempt to delay FDA approval of the generic Solodyn ANDAs. As noted above, Medicis's CEO had stated publicly that Medicis would file citizen petitions as part of a campaign to delay entry by generic rivals. And even though Medicis was ultimately unsuccessful in having the FDA stay approval of the generic Solodyn ANDAs for 30 months, Medicis's mere filing of the petition, regardless of its merits, delayed the FDA's ANDA approval process. As a matter of pattern and practice, the FDA does not approve an ANDA if a pertinent petition—even a baseless one—is pending. Adjudicating even a meritless citizen petition requires FDA to expend its time and resources, and the FDA will frequently cite public health concerns to take more time to evaluate such petitions, even ones which are ultimately meritless.

175. Medicis's 30-Month Stay Petition did, in fact, delay at least Teva's generic Solodyn ANDA. FDA approved Teva's generic Solodyn ANDA on March 17, 2009, the same date it denied Medicis's 30-Month Stay Petition. But for Medicis's second sham citizen petition, Teva would have received final approval to launch its generic Solodyn products in 45mg, 90mg, and 135mg strengths before March 17, 2009.

5. Medicis's Exclusion Payments to Teva, Sandoz, and Mylan

176. It was essential to Medicis that it stave off generic competition until November 2011, to give it time to switch the market to new versions of Solodyn for which there were no approved generic equivalents (this aspect of Medicis's scheme is discussed further in detail below). But as of January 2009, Teva, Sandoz, and Mylan had filed ANDAs for the 45mg, 90mg, and 135mg strengths of Solodyn, and Medicis expected that FDA would quickly grant approval of those ANDAs – as soon as Spring 2009. Medicis knew that FDA was likely to reject Medicis's 30-Month Stay Petition that Spring. So Medicis implemented another tactic to delay and limit generic competition from those manufacturers until November 2011.

177. Medicis's plan was straightforward. Teva, Sandoz, and Mylan were entitled under the Hatch-Waxman Act to shared 180-day exclusivity. But if all three generic manufacturers entered the market at once, they would quickly compete the price of generic Solodyn far down below the price of branded Solodyn—likely to a discount of 85% or more off the price of branded Solodyn. Moreover, if such generic entry occurred, Medicis would be likely to launch its own authorized generic product, eroding generic prices even further. Entry of multiple generics, and the consequent low prices, would of course be a boon for consumers, but it would significantly reduce the generics' profits below those that would be available if there were only one generic on the market. In light of these competitive dynamics, which are well known in the pharmaceutical industry, Medicis devised a plan that would preserve its own profits by delaying and limiting generic competition; give the generic manufacturers more profits than they could have achieved had they competed against each other; and secure these profits for itself and the generic manufacturers by robbing consumers of the competition to which they were entitled.

178. Under the guise of a litigation settlement with Teva, Medicis arranged for Teva to sell an approximate 6-month supply (for the entire market) of generic Solodyn free from

competition from Sandoz or Mylan, and free from competition from a Medicis authorized generic. After almost all the 6-month supply of the Teva product had been sold through to consumers, Medicis then arranged for Sandoz to sell a similarly limited supply of generic Solodyn free from competition from Teva or Mylan, and again free from competition from a Medicis authorized generic. Then after all the Sandoz product had been sold through to consumers, Medicis arranged for Mylan to sell an approximate 6-month supply of generic Solodyn free from competition from Teva or Sandoz, and again free from competition from a Medicis authorized generic. Organizing these seriatim periods of de facto exclusivity for each of the would-be generic competitors—periods in which the generic manufacturers did not compete against each other or against a Medicis authorized generic—was Medicis's way of paying the generics to delay unrestrained generic competition until November 2011. The seriatim periods of generic exclusivity delivered more profits to each of the generic manufacturers than if two or more of them were in the market at the same time and sharing the 180-day exclusivity. Medicis preserved most of its monopoly profits, and the generics made far more profits than competition would have allowed them. The only losers were consumers.

179. Following are the details of how Medicis acted as the ringleader of the elimination of competition among the generic manufacturers in exchange for their agreement to defer unrestrained competition until November 2011.

6. The Medicis/Teva Exclusion Payment Agreement

180. As noted above, on January 13, 2009, Medicis filed suit against Teva, along with Mylan and Sandoz, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Teva infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

181. On February 9, 2009 Teva answered the complaint, asserting that the '838 Patent is invalid and would not be infringed by its generic Solodyn products, and that Medicis improperly obtained the '838 Patent through inequitable conduct. Teva asserted that Medicis had deliberately omitted all mention of its product, Dynacin, and its own Dynacin Study, during prosecution of the '838 Patent before USPTO.

182. On March 17, 2009, FDA granted Teva final approval to market its generic 45mg, 90mg, and 135mg Solodyn products. Teva commenced shipment of its product immediately after the FDA's approval of the ANDA.

183. On or before March 17, 2009, Medicis and Teva entered the Medicis/Teva Exclusion Payment Agreement, which they subsequently memorialized in part in a written agreement dated March 18, 2009. At the time of the Agreement, neither the parties nor the court had addressed the substantive merits of the suit—beyond the initial complaint and answer.

184. Pursuant to that Agreement, Teva agreed to: (a) admit that the '838 Patent, plus the non-issued claims of twelve pending patent applications, are valid and enforceable; (b) admit that the '838 Patent is infringed by Teva's generic Solodyn products; (b) initially sell only a 6-month supply of its generic Solodyn products; and (d) thereafter delay unrestrained entry of its generic Solodyn products until November 2011, or earlier under certain circumstances.

185. As the quid pro quo for Teva's agreement to drop its challenge to the '838 Patent and thereafter delay unrestrained entry of its generic Solodyn products until November 2011, Medicis agreed to make substantial payments to Teva. The payments took the form of Medicis: (a) granting a license to Teva to sell a 6-month supply of its generic Solodyn products beginning on March 17, 2009; (b) agreeing not to grant a similar license to any other generic manufacturer during the period that Teva was negotiating with its buyers regarding the price and quantity terms

for the sale of the limited quantity of its generic Solodyn products; and (c) agreeing not to compete against Teva during this period with Medicis's own authorized generic Solodyn. The intended result of the Agreement was that Teva would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Teva, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Teva selling all of the 6-month supply at a price only slightly less than the branded price.

186. Teva has acknowledged in SEC filings that its "revenues and profits are closely tied to our ability to obtain U.S. market exclusivity for generic versions of significant products." 2009 20-F. To the extent that Teva succeeds "in being the first to market a generic version of a significant product . . . [its] sales, profits and profitability can be substantially increased in the period following the introduction of such product and prior to a competitor's introduction of an equivalent product." Teva reported that its launch of generic Solodyn was one of those "products launched with U.S. market exclusivity, or with otherwise limited competition" which contributed to Teva's 2009 operating results.

187. The purpose and effect of Medicis's payment to Teva was to delay unrestrained generic competition to Solodyn until November 2011 (or earlier under certain circumstances). Absent Teva's agreement to delay unrestrained entry into the market with generic Solodyn, Medicis would not have (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Teva was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Teva during this period with Medicis's own authorized generic Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Teva to delay unrestrained market entry of generic Solodyn.

188. Medicis then repeated this same ploy with Sandoz.

7. The Medicis/Sandoz Exclusion Payment Agreement

189. As mentioned above, Medicis had sued Sandoz on January 13, 2009, along with Teva and Mylan, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Sandoz infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

190. On February 27, 2009, Sandoz answered the complaint and asserted a counterclaim seeking a declaratory judgment that the '838 Patent is invalid and would not be infringed by its generic Solodyn products.

191. On August 13, 2009, FDA granted Sandoz final approval to market its generic 45mg, 90mg, and 135mg Solodyn products. Sandoz could have received final FDA approval earlier if it had wanted such earlier approval.

192. On or before August 17, 2009, Medicis and Sandoz entered into the Medicis/Sandoz Exclusion Payment Agreement, which they subsequently memorialized in part in a written agreement dated August 18, 2009. At the time of the Medicis/Sandoz Exclusion Payment Agreement, neither the parties nor the court had briefed or adjudicated the substantive merits of the suit.

193. Pursuant to that Agreement, Sandoz agreed to: (a) admit that the '838 Patent is valid and enforceable; (b) admit that the '838 Patent was infringed by Sandoz; (b) initially sell only a limited supply of its generic Solodyn products; and (d) thereafter delay unrestrained entry of its generic Solodyn products until November 2011, or earlier under certain circumstances.

194. As the quid pro quo for Sandoz's agreement to drop its challenge to the '838 Patent and thereafter delay entry of its generic Solodyn products until November 2011, Medicis agreed to make substantial payments to Sandoz. The payments took the form of Medicis: (a) granting a license to Sandoz to sell a limited supply of its generic Solodyn products beginning on

August 17, 2009; (b) agreeing not to grant a similar license to any other generic manufacturer during the period that Sandoz was negotiating with its buyers regarding the price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (c) agreeing not to compete against Sandoz during this period with Medicis's own authorized generic Solodyn; and (d) agreeing to make substantial payments to Sandoz pursuant to a "business partnership agreement" and "APA Agreement." The intended result of the Agreement was that Sandoz would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Sandoz, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Sandoz selling all of the limited supply at a price only slightly less than the branded price.

195. The purpose and effect of Medicis's payment to Sandoz was to delay unrestrained generic competition to Solodyn until November 2011 (or earlier under certain circumstances). Absent Sandoz's agreement to delay unrestrained entry into the market with generic Solodyn, Medicis would not have: (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Sandoz was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Sandoz during this period with Medicis's own authorized generic Solodyn; (c) agreed to make substantial payments to Sandoz pursuant to a "business partnership agreement" and "APA Agreement;" and/or (d) agreed to the terms that it did. Medicis paid Sandoz to delay unrestrained market entry of generic Solodyn.

196. Medicis then repeated this same ploy yet again with Mylan.

8. The Medicis/Mylan Exclusion Payment Agreement

197. As mentioned above, Medicis had sued Mylan on January 13, 2009, along with Teva and Sandoz, in the United States District Court for the District of Delaware, No. 1:09-CV-00033-LPS, alleging that Mylan infringed the '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg minocycline hydrochloride extended release tablets.

198. On February 3, 2009, Mylan answered the complaint and asserted a counterclaim seeking a declaratory judgment that the '838 Patent is invalid and would not be infringed by its generic Solodyn products.

199. On March 11, 2010, the USPTO issued a Notice of Intent to Issue a Reexamination Certificate stating that the USPTO had closed the reexamination proceedings and intended to issue a Reexamination Certificate as to claims 3, 4, 12 and 13 (which had been amended by Medicis during the reexamination proceedings), and new claims 19-34.

200. On May 7, 2010, Medicis received a Paragraph IV certification from Mylan stating that its majority owned subsidiary Matrix Laboratories Limited had filed an ANDA, Number 20-1467, with FDA for generic Solodyn in 65mg and 115mg strengths. In this Paragraph IV certification, Mylan alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Mylan's generic product.

201. The USPTO issued the Ex Parte Reexamination Certificate on June 1, 2010.

202. On June 14, 2010, Medicis filed suit against Mylan and Matrix in the United States District Court for the District of Delaware, No. 1:10-cv-00524-JJF-LPS, alleging that Defendants infringed the '838 Patent by submitting their ANDAs for 45mg, 90mg, and 135mg, and 65mg and 115mg generic minocycline hydrochloride extended release tablets, respectively.

203. On July 7, 2010, Medicis and Mylan submitted a stipulated motion to extend time for Mylan to answer Medicis's second complaint against it, in case 1:10-cv-00534-LPS, and to

answer an amended complaint in the first case against it, case 1:09-cv-00033, until August 16, 2010.

204. On July 8, 2010, Medicis filed an amended complaint for patent infringement in case 1:09-cv-00033-LPS against Mylan, alleging that through the filing of its ANDA 90-911 Mylan infringed certain claims of the ’838 Patent as set forth in the June 1, 2010 Reexamination Certificate.

205. On July 20, 2010, FDA granted Mylan final approval to market its generic 45mg, 90mg, and 135mg Solodyn products.

206. On or before July 21, 2010, Medicis and Mylan entered into the Medicis/Mylan Exclusion Payment Agreement, which they subsequently memorialized in part in a written agreement dated July 22, 2010. At the time of the Medicis/Mylan Exclusion Payment Agreement, the court had not issued any substantive decisions regarding the merits of Medicis’s claims or Mylan’s counterclaims.

207. Pursuant to that Agreement, Mylan agreed to: (a) admit that the ’838 Patent is valid and enforceable; (b) admit that the ’838 Patent is infringed by the products described in Mylan’s ANDA 90-911 and ANDA 20-1467; (c) initially sell only a limited supply of its 45mg, 90mg, and 135mg generic Solodyn products; (d) thereafter delay unrestrained entry of those generic Solodyn products until November 2011, or earlier under certain circumstances; and (d) delay launching its generic Solodyn products in 65mg and 115mg strengths until certain undisclosed circumstances occurred at some point in the future.

208. As the quid pro quo for Mylan’s agreement to drop its challenge to the ’838 Patent and thereafter delay entry of its generic Solodyn products until November 2011, Medicis agreed to make substantial payments to Mylan. The payments took the form of Medicis: (a) granting a

license to Mylan to sell a 6-month supply of its generic Solodyn products beginning on July 22, 2010; (b) agreeing not to grant a similar license to any other generic manufacturer during the period that Mylan was negotiating with its buyers regarding the price and quantity terms for the sale of the limited quantity of its generic Solodyn products; and (c) agreeing not to compete against Mylan during this period with Medicis's own authorized generic Solodyn. The intended result of the Agreement was that Mylan would have the only generic Solodyn product on the market, and that buyers would know, when negotiating with Mylan, that it would have the only generic Solodyn on the market during that time. The Agreement worked as planned, with Mylan selling all of the 6-month supply at a price only slightly less than the branded price.

209. The purpose and effect of Medicis's payment to Mylan was to delay unrestrained generic competition to Solodyn in 45mg, 90mg, and 135mg strengths until November 2011 (or earlier under certain circumstances) and to delay generic competition to Solodyn in 65mg and 115mg strengths. Absent Mylan's agreement to delay entry into the market with generic Solodyn, Medicis would not have: (a) agreed to refrain from granting a similar license to any other generic manufacturer during the period that Mylan was negotiating price and quantity terms for the sale of the limited quantity of its generic Solodyn products; (b) agreed not to compete against Mylan during this period with Medicis's own authorized generic Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Mylan to delay unrestrained market entry of generic Solodyn.

9. Medicis's Payments to Impax for Having Authorized Teva, Sandoz, and Mylan's Limited Sales

210. Under the Medicis/Impax Exclusion Payment Agreement, Medicis agreed not to grant a license to any other generic pharmaceutical manufacturer to sell generic Solodyn product in 45mg, 90mg, and/or 135mg strengths before Impax. If Medicis authorized another generic

manufacturer to sell such generic Solodyn products before Impax's licensed entry date of November 2011, Impax had the right to be notified and immediately launch its product.

211. Shortly after Teva launched its generic Solodyn products, Impax filed suit on May 19, 2009 against Medicis in the Superior Court of the State of Arizona in and for the County of Maricopa alleging that Medicis authorized Teva's launch of its generic Solodyn products and that such launch triggered Impax's right to enter the market before November 2011 under the Medicis/Impax Exclusion Payment Agreement. Medicis settled the case by paying Impax substantial consideration, and on June 24, 2009, Impax and Medicis submitted a stipulation for dismissal of Impax's suit with prejudice, which was entered by the court on July 1, 2009.

212. On July 27, 2010, just days after Medicis authorized the third generic manufacturer (Mylan) to sell a limited supply of its generic Solodyn products, Impax again filed suit against Medicis in the Superior Court of the State of Arizona in and for the County of Maricopa alleging that Medicis's authorization of these additional generic Solodyn products had triggered Impax's right to enter the market before November 2011 under the Medicis/Impax Exclusion Payment Agreement. After Medicis asserted counterclaims against Impax and each party moved to dismiss the other's claims—but before the court reached any substantive decision on the merits—Medicis and Impax entered a January 21, 2011 settlement of the second Arizona state court action. As in the prior settlement, Medicis again paid substantial consideration to Impax in order to end the litigation.

10. Medicis's Anticompetitive Product Hop

213. Through the various anticompetitive tactics described above, which successfully delayed the onset of unrestrained generic competition to the 45mg, 90mg, and 135mg Solodyn tablets until November 2011, Medicis literally bought itself time to execute another part of its

"three-part strategy" to defeat generic competition. Medicis bought time to destroy the market for Solodyn in 45mg, 90mg, and 135mg (*i.e.*, "legacy" strengths) and shift the market to Solodyn in 55mg, 65mg, 80mg, 105mg, and 115mg strengths (*i.e.*, "new" strengths) that did not face imminent generic competition.

214. Engaging in anticompetitive behavior was crtitical to Medicis's "product hop" scheme. It needed to delay generic entry until after it gained FDA approval to market Solodyn in the new strengths. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), available at http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10. Industry analysts in the United States echo that conclusion, warning brand manufacturers that "it is essential that the brand holder switch their patients to the new formulation prior to generic launch." Stephen Perrett, The Modified-Release Drug Delivery Landscape: The Commercial Perspective, in II MODIFIED-RELEASE DRUG DELIVERY TECHNOLOGY 1, 3 (Michael J. Rathbone et al. eds., 2d ed. 2008).

215. It was also known in the pharmaceutical industry that Medicis specifically needed to switch the market to the new strengths sufficiently in advance of generic competition in

November 2011 in order to impede generic competition – and that Medicis's Exclusion Payment Agreements with Impax, Teva, Sandoz, and Mylan had bought Medicis the time it needed to do just that. An October 8, 2010 Morningstar report, for example, stated:

> Medicis has managed to fend off generic Solodyn competition until late 2011, thanks to several deals with Teva, Sandoz (a unit of Novartis), Mylan, and Impax. By paying the generic companies to delay competition, Medicis has lengthened the runway for Solodyn. The firm may have bought enough time to get its follow-on product to Solodyn approved and launched. If Medicis can transition current Solodyn users to the next-generation product, then the picture could be more optimistic for Soloyn than we had assumed earlier.

216. Thus, knowing that the 45mg, 90mg, and 135mg strengths would soon face generic competition, Medicis, concurrent with its unlawful conduct described above, worked to market Solodyn in new strengths—starting with the 65mg and 115mg strengths, then followed by the 55mg, 80mg, and 105mg strengths. To this end, on February 29, 2008, Medicis submitted a supplemental NDA # 50-808/S-007 to the FDA seeking approval to market Solodyn in the 65 mg and 115 mg strengths. On July 23, 2009, the FDA approved Medicis's application. In August 2010, the FDA also approved a supplemental NDA # 50-808/S-013 revising the Solodyn label to include the 55mg, 80mg, and 105mg strengths.

217. The only real "benefit" of the new dose strengths was to Medicis; because the expected generic Solodyn products in legacy strengths would not be "AB-rated" to branded Solodyn in the new strengths, pharmacists could not legally substitute less-expensive generic Solodyn in one of the legacy strengths when presented with a prescription for Solodyn in one of the new strengths. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the primary means by which generic competition reduces drug prices. Disrupting this competitive mechanism was Medicis's sole reason for introducing the new Solodyn strengths.

218. But merely introducing the new dose strengths was not enough to ensure Medicis's stranglehold on the market for minocycline hydrochloride extended release tablets. Rather, Medicis aggressively destroyed demand for Solodyn legacy strengths and then converted that demand to the new Solodyn strengths using its army of sales force detailers. By August 2010, the new 65 mg and 115 mg strengths accounted for 61.5% of new Solodyn prescriptions and 58.5% of total prescriptions. By May 2011, Medicis announced that "92% of the total prescriptions in SOLODYN, moved over to the five new strengths, and 95% of new prescriptions are being written in the new strengths."

219. And then, in July 2011, shortly before legacy generics were scheduled to enter the market, Medicis stopped shipping branded Solodyn in legacy strengths altogether. In an August 8, 2011 earnings call, Medicis's CEO Shacknai explained the "new SOLODYN strategy, which [Medicis] believe[d] [would] be advantageous for the SOLODYN franchise in 2011 and beyond." Medicis's purpose in withdrawing the legacy strengths from the market was to "deplete channel inventory of branded and generic versions of the legacy strengths months ahead of the November 26 date upon which five generic companies could launch generic competitors only to these legacy strengths of SOLODYN." Shacknai continued to describe how the launch of the new strengths and market withdrawal of the legacy strengths would "have the effect of reducing the impact significantly of generic launches at the end of November 2011."

220. Medicis's draining of Solodyn in legacy strengths from the distribution channel before generic entry had an anticompetitive purpose and effect. As a result of Medicis's draining, there was little to no legacy strength Solodyn available in the marketplace from May 2011 through November 2011, when Impax, Teva, Sandoz, and Mylan entered. As explained above, Medicis took steps to make sure that physicians stopped writing prescriptions for Solodyn in legacy

strengths and started writing prescriptions for Solodyn in the new strengths instead. To the extent a physician nevertheless wrote a prescription for legacy strength Solodyn, Medicis's draining of the distribution channel ensured that there would be no legacy strength Solodyn available at the pharmacy to fill such a prescription. As a matter of good pharmacy practice and continuity of patient care, a pharmacist receiving a prescription for legacy strength Solodyn during this time would call the prescribing physician to switch the prescription to the next closest available product, namely new strength Solodyn.

221. In shifting demand to the new Solodyn strengths, Medicis knew that these strengths offered no medical, convenience, or other benefits to consumers as compared to the legacy strengths. The recommended dosage of Solodyn is approximately 1mg/kg (that is, 1 mg per 1 kg of body mass) taken once daily for twelve weeks. Dosing is thus approximately weight-based; clinical studies demonstrated that higher doses are no more effective, and may result in more adverse effects. When Medicis originally obtained approval for Solodyn, it did so by demonstrating the safety and effectiveness of the 45mg, 90mg, and 135mg strengths based on an approximate dose of 1mg/kg.

222. The new Solodyn strengths are no more effective and no safer than Solodyn in legacy strengths. The only benefit that Medicis ascribes to the new strengths is "complement[ing] the current SOLODYN lineup to offer physicians greater weight-based dosing precision of SOLODYN, [] mak[ing] SOLODYN the first and only extended release minocycline with eight FDA-approved dosing strengths." This purported "benefit," however, is pure pretext, belied by Medicis's own representations and actions.

223. Particularly telling is Medicis's opposition to a May 9, 2011 Suitability Petition filed by Lachman Consultant Services, Inc. on behalf of a generic manufacturer that wanted to file

an ANDA referencing Medicis's Solodyn NDA for different strengths (70mg and 95mg) than those the FDA had previously approved for the drug. The generic manufacturer proposed to recommend the 70mg and 95mg tablets for patients in two new weight classes, which would arguably create even greater weight-based dosing precision.

224. The FDA-approved labeling for Solodyn, which reflected all eight approved Solodyn dose strengths, contained the following dosing chart:

Patient's Weight (lbs.)	**Patient's Weight (kg)**	**Tablet Strength (mg)**	**Actual mg/kg Dose**
99-109	45 – 49	45	1 – 0.92
110-131	50-59	55	1.10-0.93
132-157	60-71	65	1.08-0.92
158-186	72-84	80	1.11-0.95
187-212	85-96	90	1.06-0.94
213-243	97-110	105	1.08-0.95
244-276	111-125	115	1.04-0.92
277-300	126-136	135	1.07-0.99

225. The Lachman petition recommended the following dosing guidelines to account for the two new weight classes associated with the 70mg and 95mg doses:

Patient's Weight (lbs.)	**Patient's Weight (kg)**	**Tablet Strength (mg)**	**Actual mg/kg Dose**
99-109	45 – 49	45	1 – 0.92
110-131	50-59	55	1.10-0.93
132-142	60-64	65	1.08-1.02
143-157	65-71	70	1.08-0.99
158-186	72-84	80	1.11-0.95
187-199	85-90	90	1.06-1
200-212	91-96	95	1.04-0.99
213-243	97-100	105	1.08-0.95
244-276	111-125	115	1.04-0.92
277-300	126-136	135	1.07-0.99

226. Medicis opposed the Lachman petition, arguing to the FDA that the new strengths were no safer or more effective than the currently available strengths – even though the creation of

two new weight classes around the 70mg and 95mg doses arguably created even more precise dosing around the recommended approximate 1mg/kg dose. Specifically, Medicis argued that recommending a 70mg dose for patients who were previously recommended to take the 65mg dose, an "otherwise equivalent" product, improperly risked doctor confusion as to safety and effectiveness, notwithstanding the arguable creation of more precise dosing, stating:

> The agency may find, for example, that singling out for higher doses patients weighing 143-157 and 200-212 lbs. – when an otherwise equivalent product (Solodyn) is currently available in lower doses – may confuse healthcare providers and patients. For example, if a patient weighing 143 lbs., who has consistently taken a 65 mg Solodyn tablet, is now guided by a generic product's labeling to take a 70 mg tablet, healthcare providers and patients may incorrectly believe that the change is based on postmarketing studies or other clinical evidence. They may also incorrectly conclude that FDA's approved 65 mg Solodyn tablet is somehow less safe or effective for a patient weighing 143 lbs. The risk of such potential confusion is unwarranted.

Medicis's Aug. 24, 2011 Suitability Petition Response at 5. In other words, it is of no importance to Medicis that a patient weighing 157 lbs, for example, would be getting 0.99 mg/kg if given a 70mg tablet—almost (if not) exactly the approximate 1mg/kg recommended dose—compared to the 0.92 mg/kg if given a 65mg; the doses are "equivalent." After the FDA granted the suitability petition, Medicis sought reconsideration and a stay of that action, characterizing the enhanced dosing precision created by the two new doses as providing "marginal benefit, if any. . . ." Medicis Mar. 7, 2013 Petition for Reconsideration and Stay of Action at 5.

227. Moreover, if Medicis were truly concerned with offering physicians greater weight-based dosing precision, it would not have stopped selling Solodyn in three of the eight approved strengths (a fact Medicis omitted from its Suitability Petition response). Without the 45mg, 90mg, and 135mg dose strengths on the market, the FDA-approved Solodyn labeling offers no guidance

to doctors as to which dose strength should be prescribed for patients weighing 99-109 pounds (recommended 45mg dose), 187-212 pounds (recommended 90mg dose) or 277-300 pounds (recommended 135mg dose).

228. Medicis publicly derided such lack of guidance in the product's labeling in its opposition to Lachman's suitability petition. Medicis argued, *inter alia*, that the "safe and effective use of the 70 and 95 mg strengths cannot be ensured" because the FDA-approved Sololdyn label instructed patients to take different tablet strengths than those proposed by the Lachman petition. Thus, under Medicis's own reasoning, the safe and effective use of Solodyn can no longer be ensured for patients in the 99-109, 187-212, or 277-300 pound ranges, who are recommended in the approved Solodyn label to take the discontinued 45mg, 90mg, and 135mg doses, respectively.

229. If the new Solodyn strengths were truly superior in that they provided physicians with greater weight-based dosing options, Medicis would have developed and marketed the new strengths sooner than it did and it would not have withdrawn the legacy strengths. Medicis's delay in developing and marketing the new Solodyn strengths, and its decision to stop shipping the legacy strengths and to shift the market to the new strengths before the onset of generic competition, confirms that Medicis developed and marketed the new Solodyn strengths not because they were superior to legacy strengths, but because they advanced Medicis's overall strategy to impair generic competition and thereby protect and expand its monopoly profits.

230. Medicis's predatory product change was intended to, and had the effect of, harming generic competition. Medicis did not expect the new dose strengths to garner it any additional sales or revenues (except those it garnered by impairing generic competition), lower its costs, or increase its efficiency. Indeed, Medicis recognized publicly that the new strengths would not

result in any "incremental revenue" associated with increased sales over and above sales of the legacy strengths (Medicis Q4 2007 Earnings Call). In fact, Medicis fully expected that, but for the effect of impairing generic competition, launching Solodyn in the new strengths would cause Medicis to lose sales and revenues, increase its costs, and decrease its efficiency. And that is indeed what happened. Medicis filed an 8-K on August 8, 2011 reflecting a revised 2011 guidance that was adjusted to reflect the "decrease in sales and profitability associated with the Legacy Strengths. The average selling price for the Legacy Strengths is approximately $200 higher than that of the current strengths." Similarly, a Medicis press release dated February 27, 2012 stated that its revenues for the three months ended December 31, 2011 decreased by approximately $17.0 million, or approximately 14.3%, compared to the same three-month period for the previous year. For the twelve months ended December 31, 2011, Medicis's revenues decreased by approximately $34.8 million, or approximately 7.2%, compared to 2010. Medicis attributed these decreases to, *inter alia*, "the Company's decision to stop shipment of the Legacy Strengths of SOLODYN to wholesalers."

231. To the extent it is even permitted to do so, Medicis cannot justify its scheme by pointing to any offsetting consumer benefit. The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Solodyn) outweigh any cognizable, nonpretextual procompetitive justifications Medicis could possibly offer. Any cognizable justifications Medicis could offer for its scheme are, in fact, pretexts. And, whatever justifications Medicis may offer, it did not need to engage in the conduct challenged in this lawsuit to achieve them.

232. As a result of Defendants' unlawful conduct, by the time generic Solodyn became available in November 2011, the prescription base for the legacy strengths was virtually non-

existent. But for this predatory product change, together with Medicis's unlawful exclusion payment agreements and other anticompetitive conduct, generic Solodyn would have been available in the market long before November 2011 and Medicis would not have launched the new Solodyn strengths or, if it had, it would have made far fewer sales of them.

11. Medicis's Additional Anticompetitive Conduct to Impair Competition to the New Strengths

233. Having bought time until November 2011 to switch the market to the new dosage strengths, Medicis next took steps to delay and suppress competition to those strengths.

234. After Medicis's predatory product change and switch strategy, the 65mg and 115mg dose strengths comprised approximately three-quarters of Solodyn sales. Medicis needed to protect these Solodyn sales from generic competitors if it was to retain the bulk of its supracompetitive Solodyn profits.

235. Knowing that Medicis's Solodyn Patents were weak, generic manufacturers lined up to get FDA approval to market generic versions of the new strengths. To continue to reap the benefits of anticompetitive scheme, Medicis would need to delay and impair this new competitive threat.

236. Medicis impaired that competition through a two-part strategy: (1) Medicis paid Teva, the first-filer with respect to the 65mg and 115mg strengths, to drop its challenge to the patents, delay entry, and "park" its 180-day exclusivity; and (2) Medicis paid the later-filing generic manufacturers, Ranbaxy, Mylan, and Lupin, not to unplug the bottleneck that Medicis and Teva created.

a. The Second Medicis/Teva Exclusion Payment Agreement

237. On November 20, 2009, Medicis received a Paragraph IV certification indicating that Teva had filed a supplement to its ANDA No. 65-485, seeking permission to market generic Solodyn in 65mg and 115mg strengths. In its Paragraph IV certification, Teva alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Teva's generic product.

238. Teva was the first generic manufacturer to file a substantially complete ANDA with respect to the 65mg and 115mg strengths. As the first filer, Teva was potentially entitled to 180-day exclusivity on the generic 65mg and 115mg strengths, provided it met the other statutory criteria and a forfeiture event did not occur.

239. On December 28, 2009, Medicis filed another sham suit against Teva in the United States District Court for the District of Maryland, No. 1:09-cv-03464, alleging that Teva infringed one or more claims of Medicis's invalid and/or unenforceable '838 Patent by submitting the ANDA.

240. On March 5, 2010, Teva answered the complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before the USPTO and unclean hands.

241. On July 9, 2010, Medicis filed an amended complaint, alleging that Teva infringed the '838 Patent as amended pursuant to the June 1, 2010 Ex parte Reexamation Certificate.

242. On August 9, 2010, Teva answered the amended complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before the USPTO and unclean hands.

243. On September 7, 2010, the USPTO issued the ’705 Patent, which was later assigned to Medicis. The FDA listed the ’705 Patent in the Orange Book for Solodyn in 45mg, 65mg, 90mg 115mg, and 135mg strengths.

244. On October 18, 2010, Medicis filed a second amended complaint, alleging that Teva infringed one or more claims of the ’838 Patent and ’705 Patent by its ANDA supplement for 65mg and 115mg generic Solodyn.

245. On November 28, 2010, Teva answered the second amended complaint, asserting defenses of non-infringement, invalidity, and unenforceability due to inequitable conduct before the USPTO and unclean hands with respect to the ’838 Patent and defenses of non-infringement and invalidity with respect to the ’705 Patent.

246. On or about February 25, 2011, Medicis and Teva entered the Second Medicis/Teva Exclusion Payment Agreement. At the time of the Agreement, neither the parties nor the court had addressed the substantive merits of the suit – beyond the complaints and answers.

247. Pursuant to that Agreement, Teva agreed to: (a) admit that the ’838 Patent and ’705 Patent are valid and enforceable; (b) admit that the ’838 Patent and ’705 Patent are infringed by Teva’s generic Solodyn 65mg and 115mg products; and (c) delay entry of generic 65mg and 115mg Solodyn products until February 2018, or earlier under certain circumstances.

248. As the quid pro quo for Teva’s agreement to drop its challenge to the ’838 Patent and ’705 Patent and thereafter delay entry of its generic 65mg and 115mg Solodyn products until February 2018, Medicis agreed to make substantial payments to Teva. The payments took various forms, including: (a) agreeing to block other generic manufacturers from entering the market with 65mg or 115mg Solodyn products until 180 days after Teva’s scheduled entry in February 2018;

and (b) agreeing not to compete against Teva with Medicis's own authorized generic 65mg or 115mg Solodyn products. The intended result of the Agreement was that Teva would have de facto 180-day exclusivity for the generic 65mg and 115mg products regardless of whether it was statutorily entitled to such exclusivity (unless later-filing generics won their patent litigations against Medicis), and that there would be no competition between Teva's products and Medicis's own authorized generic 65mg and 115mg products during the 180 days of exclusivity and beyond.

249. The purpose and effect of Medicis's payments to Teva was to delay generic competition to Solodyn 65mg and 115mg until February 2018 (or earlier under certain circumstances). Absent Teva's agreement to delay entry into the market with generic 65mg and 115mg Solodyn, Medicis would not have: (a) agreed to refrain from granting a license to any other generic manufacturer to enter the market before Teva's scheduled entry in February 2018; (b) agreed not to compete against Teva with Medicis's own authorized generic 65mg and 115 Solodyn; and/or (c) agreed to the terms that it did. Medicis paid Teva to delay market entry of generic 65mg and 115mg Solodyn.

250. The Second Medicis/Teva Exclusion Payment Agreement created a bottleneck that impaired later-filing generics' ability to get their 65mg and 115mg products onto the market. Medicis also ensured that none of those later filers would dislodge the bottleneck. Medicis used a favorite tactic – more exclusion payments.

b. The Medicis/Ranbaxy Exclusion Payment Agreement

251. Medicis filed a sham suit against Ranbaxy on June 11, 2009 in the United States District Court for the District of Delaware, No. 1:09-CV-00435-JJF, alleging that Ranbaxy infringed one or more claims of Medicis's invalid and/or unenforceable '838 Patent by submitting to FDA its ANDA for 135mg Solodyn.

252. On July 1, 2009, Ranbaxy answered the complaint, asserting that the '838 Patent was invalid and would not be infringed by Ranbaxy's generic Solodyn product, and that Medicis's claims were barred by the doctrine of unclean hands and patent misuse. Ranbaxy asserted that Medicis had deliberately omitted all mention of its product, Dynacin, and its own Dynacin Study, during prosecution of the '838 Patent before USPTO. Further, Ranbaxy asserted a counterclaim against Medicis seeking a declaratory judgment that the '838 Patent was invalid and unenforceable.

253. On September 24, 2009, Medicis's suit against Ranbaxy was joined with Medicis's suit against Teva, Sandoz, and Mylan in the same court, No. 1:09-vc-00033-JJF.

254. On January 5, 2010, Medicis received Ranbaxy's Paragraph IV certification stating that Ranbaxy had supplemented its ANDA to include the 45mg and 90mg strengths of Solodyn.

255. On February 16, 2010 Medicis sued Ranbaxy in the United States District Court for the District of Delaware, No. 1:10-CV-00120-JJF, alleging that Ranbaxy infringed one or more claims of Medicis's '838 Patent by submitting to FDA its supplemented ANDA for 45mg and 90mg Solodyn.

256. Ranbaxy answered Medicis's complaint on April 16, 2010.

257. On April 15, 2010, Medicis received Ranbaxy's Paragraph IV certification stating that Ranbaxy had supplemented its ANDA to include the 65mg and 115mg strengths of Solodyn.

258. On May 4, 2010, Medicis and Ranbaxy formally entered the Medicis/Ranbaxy Exclusion Payment Agreement.

259. Pursuant to the Agreement, Ranbaxy agreed to: (a) admit that the '838 Patent was valid and enforceable and covered Ranbaxy's products under ANDA 91-118; (b) be permanently enjoined from any distribution of generic versions of Solodyn except pursuant to the Agreement;

(c) delay launching its generic Solodyn products in the 45mg, 90mg, and 135mg strengths until November 2011, or earlier under certain circumstances; and (d) delay launching its generic Solodyn products in the 65mg and 115mg strengths until after Teva launched its generic versions of those products.

260. As the quid pro quo for Ranbaxy's agreement to drop its challenge to the '838 Patent and delay entry of its 45mg, 90mg, and 135mg generic Solodyn products until November 2011 and its 65mg and 115mg products until after Teva launched its generic versions of those strengths, Medicis paid Ranbaxy. That payment took the form of a license to Ranbaxy to make and sell a "branded proprietary dermatology product currently under development by Ranbaxy . . . commencing on the later of August 2011 or upon the sale of such product by Ranbaxy following approval by the FDA."

261. The purpose and effect of the Medicis/Ranbaxy Exclusion Payment Agreement was to: (a) delay generic competition to the 45mg, 90mg, and 135mg Solodyn strengths until November 2011 (or earlier under certain circumstances); (b) delay generic competition to the 65mg and 115mg Solodyn strengths; (c) ensure that Ranbaxy would not obtain a court decision that would trigger the start of Teva's 180-day exclusivity. Absent Ranbaxy's agreement to delay entry into the market with generic Solodyn, Medicis would not have granted Ranbaxy a license to make and sell Medicis's "branded proprietary dermatology product" that was under development by Ranbaxy, or would not have granted that license on the terms that it did. Medicis paid Ranbaxy for delayed market entry of generic Solodyn.

c. The Medicis/Lupin Exclusion Payment Agreement

262. On October 8, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed ANDA No. 19-424 with FDA for generic Solodyn in 45mg, 90mg,

and 135mg strengths. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

263. On November 17, 2009, Medicis filed a sham suit against Lupin in the United States District Court for the District of Maryland, No. 1:09-cv-03062, alleging that Lupin infringed one or more claims of Medicis's invalid and/or unenforceable '838 Patent by submitting to FDA the ANDA for 45mg, 90mg, and 135mg Solodyn.

264. On March 4, 2010, Lupin answered the complaint, asserting defenses of non-infringement, invalidity, and unenforceability and alleging a counterclaim seeking a declaratory judgment that the '838 Patent would not be infringed by its generic Solodyn products, the claims of the '838 Patent are invalid, and the '838 Patent is unenforceable due to inequitable conduct before the USPTO.

265. On November 24, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed an amendment and/or supplement to its ANDA Number 19-424, for 65mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

266. On December 23, 2009, Medicis received a Paragraph IV certification from Lupin giving notice that it had filed an amendment and/or supplement to its ANDA Number 19-424, for 115mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product.

267. Medicis amended its complaint to allege that Lupin's 65mg and 115mg generic products would also infringe Medicis's '838 Patent.

268. On March 4, 2010, Lupin answered the complaint, asserting defenses of non-infringement, invalidity, and unenforceability and asserting a counterclaim seeking a declaratory

judgment that the ’838 Patent is invalid, not infringed, and unenforceable due to inequitable conduct before the USPTO.

269. On July 1, 2010, Medicis filed its third amended complaint, alleging that Lupin infringed the ’838 Patent as amended pursuant to the June 1, 2010 Ex parte Reexamation Certificate.

270. On September 7, 2010, the USPTO issued the ’705 Patent, which was later assigned to Medicis. The FDA listed the ’705 Patent in the Orange Book for Solodyn after Medicis submitted information regarding the ’705 Patent to the FDA on September 9, 2010 for Solodyn in 45mg, 65mg, 90mg 115mg, and 135mg strengths.

271. On or about September 17, 2010, Medicis received notice from Lupin stating that its ANDA and supplements were submitted with a Paragraph IV certification that the ’705 Patent is not infringed.

272. On October 18, 2010, Medicis filed its fourth amended complaint, alleging that Lupin’s proposed generic Solodyn products in 45mg, 65mg, 90mg, 115mg, and 135mg strengths would infringe the ’838 and ’705 Patents.

273. On December 3, 2010, Medicis received a Paragraph IV certification informing it that Lupin had filed an amendment and/or supplement to ANDA Number 19-424, for 55mg and 80mg generic Solodyn. Lupin’s Paragraph IV certification alleged that the ’838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin’s generic product and that the ’705 Patent is not infringed.

274. On January 10, 2011, Medicis filed its fifth amended complaint, alleging that Lupin’s 55mg and 80mg generic product would infringe the ’838 and ’705 Patents. Medicis further alleged that Lupin was the first to file an ANDA with respect to the 55 mg strength.

275. On January 24, 2011, Medicis received a Paragraph IV certification informing it that Lupin had filed an amendment and/or supplement to ANDA Number 19-424, for 105mg generic Solodyn. Lupin's Paragraph IV certification alleged that the '838 Patent was invalid, unenforceable, and/or would not be infringed by Lupin's generic product and that the '705 Patent was not infringed.

276. On March 2, 2011, Medicis filed its sixth amended complaint, alleging that Lupin's 105mg generic Solodyn product would infringe the '838 and '705 Patents.

277. On July 21, 2011, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement. At the time of the Agreement, neither the parties nor the court had addressed the substantive merits of the suit.

278. Pursuant to the Agreement, Lupin agreed to: (a) admit that the '838 and '705 patents (and certain other "patent rights" including other patents and patent applications) are valid, enforceable, and infringed by Lupin's proposed generic Solodyn products; (b) delay launching its generic Solodyn products in 45mg, 90mg, and 135mg strengths until November 26, 2011, or earlier under certain circumstances; (c) delay launching its generic Solodyn products in 65mg and 115mg strengths until February 2018, or earlier under certain circumstances; (d) delay launching its generic Solodyn products in 55mg, 80mg, and 105mg strengths until February 2019, or earlier under certain circumstances. Notwithstanding the foregoing admissions with respect to Medicis's patent rights, Lupin explicitly retained its right to maintain its Paragraph IV certification, thereby creating an FDA approval bottleneck on the 55mg strength of generic Solodyn.

279. As the quid pro quo for Lupin's agreement to drop its challenge to the '838 and '705 Patents and delay marketing its generic Solodyn products, Medicis agreed to pay Lupin tens

of millions of dollars or more. Medicis's payments to Lupin under the Agreement took a variety of forms.

280. First, Medicis paid Lupin an "upfront fee" of $20 million under the guise of a Joint Development Agreement providing for the collaboration and development of "multiple novel therapeutic products."

281. Second, in April 2012, Medicis paid Lupin $2.5 million in connection with the parties' entering into the March 30, 2012 Amended and Restated Joint Development Agreement.

282. Third, Medicis agreed to pay Lupin up to $35.5 million in milestone payments.

283. Fourth, to the extent any products are commercialized under the Agreement, Medicis agreed to pay Lupin royalties on sales of such products.

284. Although Medicis's payments to Lupin under the Exclusion Payment Agreement are characterized as payments for the collaboration on and development of additional products, that characterization is pretextual. In fact, the payments from Medicis to Lupin were for Lupin's agreement to delay generic competition. Absent Lupin's agreement to delay entry into the market with generic Solodyn, Medicis would not have entered the Joint Development Agreement with Lupin and/or would not have agreed to the price and/or other terms that it did under those provisions of the Agreement. Medicis paid Lupin for delayed market entry of generic Solodyn.

ANTICOMPETITIVE EFFECTS OF THE SCHEME

285. Medicis's overarching anticompetitive scheme, and the Generic Defendants' participation in it, delayed and substantially diminished the sale of generic Solodyn products in the United States, and unlawfully enabled Medicis to sell Solodyn at artificially inflated prices. But for Defendants' illegal conduct, generic manufacturers would have been able to enter the market unimpeded (either by entering while the patent litigation was pending, or prevailing in the patent

litigation and then entering), and compete on the merits against Solodyn. Generic competitors would also have been able to compete far earlier than they did, and additional generic competitors would have entered the market (earlier) thereafter. Moreover, if Medicis would have continued to pursue the sham litigations against the Generic Defendants, Medicis would have lost those litigations. As to the Generic Defendants' willingness to enter before the end of the patent litigation, Teva, Lupin, and Mylan have all introduced generic products while patent litigation was ongoing, and it was well-known within the drug industry that the Generic Defendants were willing to do so. For example, Defendant Teva, has launched at-risk over twenty times, including a September 2005 launch of a generic version of Allegra prior to resolution of the patent litigation. See Press Release, "Teva and Barr Announce Launch of Generic Allegra Tablets By Teva Under Agreement With Barr," available at http://www.tevapharm.com/pr/2005/pr_544.asp. Defendant Lupin launched generic Fortamet at-risk on September 30, 2011. *See* Shionogi & Co., Ltd. and Shionogi Inc. Announce a Favorable Decision In FORTAMET® Preliminary Injunction Proceedings, Business Wire, Dec. 7, 2011, available at http://www.businesswire.com/news/home/20111207005999/en/Shionogi-Ltd.-Shionogi-Announce-Favorable-Decision-FORTAMET%C2%AE. Defendant Mylan launched generic Amrix at-risk in May 2011. Mylan Launches Generic Amrix; Cephalon Files Motion for TRO, Orange Book Blog, May 15, 2011, available at http://www.orangebookblog.com/2011/05/mylan-launches-generic-amrix-cephalon-files-motion-for-tro.html.

286. Medicis would not have prevailed against one or more of the Generic Defendants in the patent litigation; In Hatch-Waxman patent litigation, generic firms have prevailed, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied. Federal Trade Commission,

Generic Drug Entry Prior to Patent Expiration, at 20 (July 2002), available at ww.ftc.gov/os/2002/07/genericdrugstudy.pdf. Medicis was no doubt aware that both as a general matter, and because of the particular and severe problems it faced in its patent litigation against the Generic Defendants, that it most likely would not be able to keep the Generic Defendants off the market solely by using its patent (by, for example, obtaining an injunction from a court).

287. Alternatively, but for the substantial payments Medicis made to the Generic Defendants in exchange for their agreements to delay marketing generic Solodyn products, Medicis and one or more of the Generic Defendants would have agreed to an unrestrained licensed entry date significantly earlier than November 2011 for Solodyn in the legacy strengths (and, to the extent Medicis would have even marketed the new dose strengths but for Defendants' unlawful conduct, significantly earlier than February 2018 for the 65mg and 115mg strengths and February 2019 for the 55mg, 80mg, and 105mg strengths). Without the payments, which were the quid pro quo for the delay, and absent an at-risk launch, one or more of the Generic Defendants would have insisted on, and received, earlier, unrestrained licensed entry. That Defendants did not need to resort to payments from Medicis to the Generic Defendants in order to resolve their patent litigation is confirmed by empirical studies. According to the FTC, "the vast majority of patent settlements (greater than 70%)" are resolved "without compensation to the generic manufacturer." FTC Bureau of Competition, Overview of Agreements Filed in FY 2012, at 2 (Jan. 17, 2013), available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf. FTC analyses also show that in 2004 and 2005, twenty-seven out of thirty, or 90% of agreements between brand and generic manufactures settling patent disputes contained no anticompetitive payment from the brand to the generic manufacturer. See FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of

Agreements Filed in FY 2005: A Report by the Bureau of Competition (2006), available at http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf; FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by the Bureau of Competition (2005), available at http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf. Many of those twenty-seven agreements allowed for sustained entry of a generic drug well before the date of patent expiration. Those agreements took various forms, but many agreements resulted in either: (a) split patent life whereby the generic would enter the market before the expiry of the challenged patent; or (b) unrestricted generic entry immediately upon or very soon after the settlement, sometimes accompanied by a royalty payment from the generic manufacturer to the brand manufacturer. Defendants here could and likely would have entered into an agreement containing such provisions but for their entry into the exclusion agreements.

288. Defendants' conduct unlawfully prevented purchasers of Solodyn from obtaining the benefits of unimpaired generic competition. By delaying the onset of unrestrained generic competition and reducing the prescription base, Defendants deprived would-be generic versions of the most efficient means of distribution under the governing statutory and regulatory regime. But for other aspects of Medicis's anticompetitive scheme, which bought Medicis the time necessary to effectuate its unlawful switch strategy, Medicis would not have developed or marketed Solodyn in the new strengths and switched a substantial portion of sales to that product, and/or generic Solodyn in legacy strengths would have entered the market before Solodyn in the new strengths, and Medicis would have been able to switch no or few prescriptions to the new strengths.

289. Defendants' scheme and unlawful payments harmed Plaintiff and the Class by depriving them of: (1) a market in which manufacturers and distributors of generic drugs make

their decisions about challenging patents and entering markets free from the influence of unlawful payments; and (2) the most cost efficient means of distribution. Contrary to the purpose of the Hatch-Waxman Act, the anticompetitive scheme and payments have enabled Defendants to: (a) delay the entry of less expensive generic versions of Solodyn in the United States; (b) fix, raise, maintain, or stabilize the price of Solodyn; (c) allocate 100% or nearly 100% of the U.S. market for minocycline hydrochloride extended release tablets to Medicis.

290. Defendants' unlawful conduct has delayed and diminished the sale of generic Solodyn in the United States, and unlawfully enabled Medicis to sell Solodyn at artificially inflated, supracompetitive prices. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

ANTITRUST IMPACT

291. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of brand Solodyn directly from Defendants and/or purchased substantial amounts of AB-rated Solodyn bioequivalent generic directly from Defendants or others. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their minocycline hydrochloride extended release tablets requirements. Those prices were substantially greater than those that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand Solodyn was artificially inflated by Defendants' illegal conduct; (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Solodyn; and/or (3) the price of AB-rated Solodyn generic was artificially inflated by Defendants' illegal conduct.

292. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

INTERSTATE AND INTRASTATE COMMERCE

293. At all material times, Medicis manufactured, promoted, distributed, and sold substantial amounts of Solodyn in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

294. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Solodyn and/or AB-rated bioequivalents.

295. In furtherance of their efforts to monopolize and restrain competition in the market for Solodyn and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

MARKET POWER

296. At all relevant times, Medicis had substantial market power (i.e., monopoly power) with respect to minocycline hydrochloride extended release tablets because it had the power to maintain the price of the drug it sold as Solodyn at substantially supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

297. A small but significant, non-transitory price increase above the competitive level for Solodyn by Medicis would not have caused a loss of sales sufficient to make the price increase unprofitable.

298. Solodyn does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Solodyn.

299. The differing efficacy, safety, and side effect profiles of different treatments for non-nodular moderate to severe acne play a critical role in doctors' selection of the most appropriate treatment for a particular patient. The FDA does not consider these various products to be bioequivalent.

300. For clinical reasons, among others, physicians and patients prefer Solodyn to other products designed to treat non-nodular severe to moderate acne. Due to, among other reasons, its once-daily dosing of extended release tablets with a unique dissolution profile that provides an effective dose with reduced side effects, Solodyn is significantly differentiated from all products other than AB-rated generic versions of Solodyn. And as described in detail above, the "price disconnect" very substantially reduces the price elasticity of demand between Solodyn and other products designed to treat non-nodular severe to moderate acne.

301. The existence of other products designed to treat non-nodular severe to moderate acne has not significantly constrained Medicis's pricing of Solodyn. At all relevant times, Medicis's price for Solodyn has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs. Medicis has never lowered the price of Solodyn in response to the pricing of other branded products indicated for the treatment of non-nodular severe to moderate acne (or the generic versions of those other products).

302. Medicis needed to control only Solodyn and its AB-rated generic equivalents, and no other products, in order to maintain the price of Solodyn profitably at substantially supracompetitive prices. Only the market entry of a competing, AB-rated generic version of

Solodyn would render Medicis unable to profitably maintain substantially supracompetitive prices for Solodyn.

303. Medicis knew that entry of a generic version of Solodyn would be a uniquely significant market event. The entry of other products indicated to treat non-nodular severe to moderate acne (or generic versions of those other brands) did not take substantial sales from Solodyn or cause Medicis to lower its price. But Medicis predicted that entry of generic Solodyn would immediately cause branded Solodyn to lose well more than half of its unit sales. Likewise, the Generic Defendants estimated that their generic versions of Solodyn would take essentially all of their sales from branded Solodyn and few if any sales from other branded products indicated to treat non-nodular severe to moderate acne.

304. Defendants predicted that the competitive impact of a generic version on branded Solodyn would be substantial. Among other things, all Defendants predicted that entry of generic Solodyn would deliver hundreds of millions of dollars of savings to consumers.

305. At all relevant times, Medicis has sold Solodyn at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

306. Medicis had, and exercised, the power to exclude and restrict competition to Solodyn and its AB-rated bioequivalents.

307. Medicis, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

308. To the extent that Plaintiff is legally required to prove substantial market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is minocycline hydrochloride extended release tablets or narrower markets

contained therein. During the relevant time, Medicis has been able to profitably maintain the price of minocycline hydrochloride extended release tablets substantially above competitive levels.

309. The relevant geographic market is the United States and its territories.

310. At all relevant times, until the entry of AB-rated generic competition, Medicis's market share in the relevant market was and remains 100% or nearly 100%, implying a substantial amount of market power.

CLASS ACTION ALLEGATIONS

311. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of a Class defined as follows:

> All persons or entities in the United States and its territories who purchased Solodyn 45mg, 65mg, 80 mg, 90mg, 105mg, 115mg, and/or 135mg tablets directly from Medicis and/or Generic Defendants at any time from February 3, 2009 until the anti-competitive effects of Defendants' conduct cease (the "Class").

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

312. Members of the Class are so numerous and geographically dispersed that joinder is impracticable. Further, the Class is readily identifiable from information and records in the possession of Defendants.

313. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for minocycline hydrochloride extended release tablets and were deprived of the benefits of earlier and *more* robust competition from cheaper generic versions of minocycline hydrochloride extended release tablets as a result of Defendants' wrongful conduct.

314. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

315. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

316. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate.

317. Questions of law and fact common to the Class include, but are not limited to:

a. whether Defendants conspired to willfully maintain and/or enhance Medicis's monopoly power over Solodyn and its generic equivalents;

b. whether Medicis obtained the '838 Patent by deceiving USPTO;

c. whether Medicis improperly listed the '838 Patent in FDA's Orange Book;

d. whether Medicis engaged in baseless patent litigation against one or more of the Generic Defendants;

e. whether Medicis filed one or more objectively baseless sham citizen petitions with FDA to delay generic competition to Solodyn;

f. whether Defendants conspired to suppress generic competition to Solodyn;

g. whether Defendants entered into an unlawful agreement in restraint of trade;

h. whether, pursuant to the Agreements, the Generic Defendants agreed to delay their entry into the market with generic Solodyn ;

i. whether, pursuant to the Agreements, Medicis compensated the Generic Defendants;

j. whether Medicis's compensation to the Generic Defendants was for any purpose other than delayed entry of generic Solodyn;

k. whether Medicis's compensation to the Generic Defendants was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;

l. whether the Agreements created a bottleneck to generic competition;

m. whether one or more of the Agreements is illegal;

n. whether Medicis's introduction of new strengths of Solodyn was intended to impede generic competition;

o. whether Medicis's introduction of new strengths of Solodyn did in fact impede generic competition;

p. whether Medicis possessed substantial market power over Solodyn and its AB-rated generic equivalents;

q. whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

r. whether Medicis maintained monopoly power over Solodyn by unlawfully suppressing generic competition to Solodyn;

s. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

t. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Class; and

u. the quantum of aggregate overcharge damages to the Class.

318. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

319. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Monopolization Under Sherman Act - Section 2
(against Medicis)

320. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

321. At all relevant times, Medicis possessed substantial market power (i.e., monopoly power) in the relevant market.

322. As alleged above, Medicis knowingly and willfully engaged in an anticompetitive scheme designed to unlawfully extend and maintain its monopoly power. This scheme included, *inter alia*:

a. obtaining the ’838 Patent by making deliberate misrepresentations and omissions to the Patent and Trademark Office;

b. improperly submitting the invalid and/or unenforceable ’838 Patent to the FDA for Orange Book listing;

c. enforcing the ’838 Patent in bad faith against its prospective generic competitors by filing objectively baseless sham patent suits solely to delay generic competition to Solodyn;

d. filing two objectively baseless sham citizen petitions with FDA solely to delay generic competition to Solodyn;

e. entering multiple Exclusion Payment Agreements with, between, and among its prospective generic competitors relating to Solodyn in legacy strengths;

f. engaging in a predatory product hop from Solodyn in legacy strengths to Solodyn in the “new” dosage strengths; and

g. entering multiple Exclusion Payment Agreements with, between, and among its prospective generic competitors relating to Solodyn in the “new” dosage strengths.

323. Through the overarching anticompetitive scheme, as alleged extensively above, Medicis willfully maintained its monopoly power through restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Solodyn.

324. The goal, purpose, and effect of Medicis's scheme was to delay and impair the sale of generic Solodyn products in the United States at prices significantly below Medicis's prices for Solodyn, thereby effectively preventing the average market price of extended-release minocycline hydrochloride products from declining dramatically.

325. By engaging in the foregoing conduct, Medicis has intentionally and wrongfully maintained monopoly power in the relevant market in violation of Section 2 of the Sherman Act.

326. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Defendants' conduct unlawful.

SECOND CLAIM FOR RELIEF

For Attempted Monopolization Under Sherman Act - Section 2
(against Medicis)

327. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

328. At all relevant times, Medicis possessed substantial market power (*i.e.*, monopoly power) or possessed a dangerous probability of achieving monopoly power.

329. With the specific intent to achieve a monopoly, Medicis attempted to acquire and/or willfully maintain monopoly power by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for Solodyn.

330. The goal, purpose, and effect of Medicis's scheme was to delay and impair the sale of generic Solodyn products in the United States at prices significantly below Medicis's prices for Solodyn, thereby effectively preventing the average market price for Solodyn and its generic equivalent products from declining dramatically.

331. By engaging in the foregoing conduct, Medicis has intentionally and wrongfully attempted to monopolize the relevant market in violation of the Sherman Act.

332. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Defendants' conduct unlawful.

THIRD CLAIM FOR RELIEF
For Conspiracy to Monopolize Under Sherman Act - Section 2
(against all Defendants)

333. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

334. At all relevant times, Medicis possessed substantial market power (*i.e.*, monopoly power). Medicis possessed the power to control prices in, prevent prices from falling in, and exclude competitors.

335. Through the overarching anticompetitive scheme, including the Exclusion Payment Agreements with Impax, Lupin, Sandoz, Mylan, Matrix, Teva, Ranbaxy, and Barr, Defendants knowingly and intentionally conspired to maintain and enhance Medicis's monopoly power in the relevant market by delaying and impairing market entry of generic Solodyn. The unlawful Exclusion Payment Agreements between Defendants allocated 100% or nearly 100% of the relevant market in the United States; delayed and impaired the sales of generic Solodyn products; and fixed the price at which Plaintiff and other members of the Class would pay at the higher, branded price.

336. The goal, purpose, and/or effect of the Exclusion Payment Agreements was to maintain and extend Medicis's monopoly power in the United States market for Solodyn and its generic equivalents. The Exclusion Payment Agreements prevented and/or delayed generic competition to Solodyn and enabled Medicis to continue charging supracompetitive prices for extended-release minocycline hydrochloride products without a loss of sales sufficient to make those prices unprofitable.

337. Defendants specifically intended that the Exclusion Payment Agreements would maintain Medicis's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

338. Defendants each committed at least one overt act in furtherance of the conspiracy.

339. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance and conspiracy to maintain Medicis's monopoly power, Plaintiff and

members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

340. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the Sherman Act.

341. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Defendants' conduct unlawful.

THIRD CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against all Defendants)

342. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

343. By entering the Exclusion Payment Agreements, Medicis engineered an agreement with, between, and among the Generic Defendants not to compete with each other and to delay generic entry, which constituted a continuing illegal contract, combination, and conspiracy in restraint of trade.

344. In or about November 2008 and at times before the formal execution thereof, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to

make substantial payments to Impax in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

345. In or about March 2009 and at times before the formal execution thereof, Medicis and Teva entered into the Medicis/Teva Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Teva in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

346. In or about February 2011 and at times before the formal execution thereof, Medicis and Teva entered into the Second Medicis/Teva Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Teva in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby

protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plainitff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

347. In or about August 2009 and at times before the formal execution thereof, Medicis and Sandoz entered into the Medicis/Sandoz Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Sandoz in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

348. In or about July 2010 and at times before the formal execution thereof, Medicis and Mylan entered into the Medicis/Mylan Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Mylan in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

349. In or about May 2010 and at times before the formal execution thereof, Medicis and Ranbaxy entered into the Medicis/Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to

make substantial payments to Mylan in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

350. In or about July 2011 and at times before the formal execution thereof, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Lupin in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

351. The purpose and effect of the payments flowing from Medicis to Generic Defendants under the Agreements was to delay and impair generic competition to Solodyn, and there is no legitimate, non-pretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

352. The Exclusion Payment Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

353. As a direct and proximate result of Defendants' unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and

members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

354. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

355. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Defendants' conduct unlawful.

FIFTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against Medicis and Impax)

356. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

357. In or about November 2008 and at times before the formal execution thereof, Medicis and Impax entered into the Medicis/Impax Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Impax in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States;

(b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

358. The purpose and effect of the payments flowing from Medicis to Impax under their agreements was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

359. The Medicis/Impax Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

360. As a direct and proximate result of Medicis and Teva's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

361. By engaging in the foregoing conduct, Medicis and Impax have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

362. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis and Impax's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis and Impax's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Medicis and Impax's conduct unlawful.

SIXTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against Medicis and Teva)

363. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

364. In or about March 2009 and at times before the formal execution thereof, Medicis and Teva entered into the Medicis/Teva Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Teva in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

365. In or about February 2011 and at times before the formal execution thereof, Medicis and Teva entered into the Second Medicis/Teva Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Teva in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plainitff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

366. The purpose and effect of the payments flowing from Medicis to Teva under their agreements was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

367. The first and second Medicis/Teva Exclusion Payment Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

368. As a direct and proximate result of Medicis and Teva's unlawful restraints of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

369. By engaging in the foregoing conduct, Medicis and Teva have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

370. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis and Teva's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis and Teva's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Medicis and Teva's conduct unlawful.

SEVENTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against Medicis and Sandoz)

371. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

372. In or about August 2009 and at times before the formal execution thereof, Medicis and Sandoz entered into the Medicis/Sandoz Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Sandoz in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiff and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

373. The purpose and effect of the payments flowing from Medicis to Sandoz under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

374. The Medicis/Sandoz Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

375. As a direct and proximate result of Medicis and Sandoz's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

376. By engaging in the foregoing conduct, Medicis and Sandoz have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

377. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis and Sandoz's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Medicis and Sandoz's conduct unlawful.

EIGHTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against Medicis and Mylan)

378. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

379. In or about July 2010 and at times before the formal execution thereof, Medicis and Mylan entered into the Medicis/Mylan Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Mylan in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis

from unrestrained generic competition; and (c) fix the price at which Plaintiffs and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

380. The purpose and effect of the payments flowing from Medicis to Mylan under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

381. The Medicis/Mylan Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

382. As a direct and proximate result of Medicis and Mylan's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

383. By engaging in the foregoing conduct, Medicis and Mylan have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

384. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis and Mylan's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis and Mylan's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Medicis and Mylan's conduct unlawful.

NINTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against Medicis and Ranbaxy)

385. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

386. In or about May 2010 and at times before the formal execution thereof, Medicis and Ranbaxy entered into the Medicis/Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Mylan in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

387. The purpose and effect of the payments flowing from Medicis to Ranbaxy under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

388. The Medicis/Ranbaxy Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

389. As a direct and proximate result of Medicis and Ranbaxy's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

390. By engaging in the foregoing conduct, Medicis and Ranbaxy's have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

391. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis and Ranbaxy's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis and Ranbaxy's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Medicis and Ranbaxy's conduct unlawful.

TENTH CLAIM FOR RELIEF

For Conspiracy and Combination in Restraint of Trade Under Sherman Act - Section 1 (against Medicis and Lupin)

392. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

393. In or about July 2011 and at times before the formal execution thereof, Medicis and Lupin entered into the Medicis/Lupin Exclusion Payment Agreement, a continuing illegal contract, combination, and conspiracy in restraint of trade under which Medicis agreed to make substantial payments to Lupin in exchange for its agreement to delay bringing its generic version of Solodyn to the market, the purpose and effect of which was to: (a) allocate to Medicis 100% or nearly 100% of the market for Solodyn and its generic equivalents in the United States; (b) delay or impair the sale of generic versions of Solodyn in the United States, thereby protecting Medicis from unrestrained generic competition; and (c) fix the price at which Plaintiffs and the Class would pay for Solodyn and its generic equivalents at supracompetitive levels.

394. The purpose and effect of the payments flowing from Medicis to Lupin under their agreement was to delay and impair generic competition to Solodyn, and there is no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payments that outweighs their harmful effects.

395. The Medicis/Ranbaxy Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

396. As a direct and proximate result of Medicis and Lupin's unlawful restraint of trade and unlawful maintenance of and conspiracy to maintain Medicis's monopoly power, Plaintiff and members of the Class paid artificially inflated prices for Solodyn and its generic equivalents as described herein, and were harmed as a result.

397. By engaging in the foregoing conduct, Medicis and Lupin have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the Sherman Act.

398. Plaintiff and members of the Class have been injured in their business or property by reason of Medicis and Lupin's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release minocycline hydrochloride products; and (2) paying higher prices for extended-release minocycline hydrochloride products than they would have paid in the absence of Medicis and Lupin's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Medicis and Lupin's conduct unlawful.

DEMAND FOR JUDGMENT

399. WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully pray the Court for a judgment that:

a) Adjudges and decrees that the conduct alleged herein are unlawful restraints of trade in violation of Section 1 of the Sherman Act; and willful acts of monopolization in violation of Section 2 of the Sherman Act;

b) Determines that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare Plaintiff to be the representative of the Class;

c) Grants each member of the Class recover three-fold the damages determined to have been sustained by each of them;

d) Enters joint and several judgments against Defendants in favor of Plaintiff and the Class;

e) Awards Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

f) Grants such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed Class demands a trial by jury on all issues so triable.

Dated: July 23, 2013

Respectfully Submitted,

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